

1                   IN THE UNITED STATES DISTRICT COURT  
                  FOR THE NORTHERN DISTRICT OF OHIO  
2                   EASTERN DIVISION

\* \* \* \* \*

In re: NATIONAL PRESCRIPTION MDL NO. 2804  
OPIATE LITIGATION

This document relates to: Case No.  
17-MD-2804

All Cases

\* \* \* \* \*

\* \* \*

WEDNESDAY, APRIL 24, 2019

\* \* \*

HIGHLY CONFIDENTIAL

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

\* \* \*

Videotaped deposition of SCOTT WEXELBLATT, M.D., held at the offices of Vorys, Sater, Seymour and Pease, Suite 3500, 301 East Fourth Street, Great American Tower, Cincinnati, Ohio, commencing at 9:23 a.m., on the above date, before Kimberley Keene, Registered Professional Reporter.

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1 THE VIDEOGRAPHER: We are now on the record.  
2 My name is Melinda Sindiong. I'm the videographer for  
3 Golkow Technologies. Today is April 24, 2019. The  
4 time is 9:23. The video deposition is being held in  
5 Cincinnati, Ohio in the matter of National  
6 Prescription Opiate Litigation, and this is for the  
7 U.S. District Court, Northern District of Ohio,  
8 Eastern Division.

9 The deponent is Scott L. Wexelblatt, M.D.,  
10 and the counsel will be noted on the stenographic  
11 record.

12 The court reporter is Kim Keene, and will now  
13 swear in the witness and we can proceed.

14

15 \* \* \*

16 SCOTT WEXELBLATT, M.D., after having first  
17 been duly administered an oath, testified as follows:

18 THE WITNESS: Yes.

19 \* \* \*

20

21 EXAMINATION

22 BY MR. ALEXANDER:

23 Q. State your name for the record, please.

24 A. Scott Wexelblatt.

25 Q. And your professional address?



1 A. 3333 Burnet Avenue, Cincinnati, Ohio.

2 Q. How are you doing this morning?

3 A. Great. How are you?

4 Q. Awesome. Thanks for your patience while we  
5 got all of the moving pieces started.

6 Do you understand that you are here to be  
7 deposed in connection with an expert report that was  
8 served with your name on it a couple of weeks ago from  
9 some cases brought by Cuyahoga and Summit County?

10 A. Yes.

11 Q. The report that we got was dated and had a  
12 signature on it from March 25th.

13 Does that sound like the time that you did an  
14 expert report?

15 A. Yes.

16 Q. Is the expert report that you completed  
17 around March 25th of this year the only expert report  
18 that you have completed in connection with opioid  
19 litigation?

20 A. Yes.

21 Q. When I use the term "opioid," does that have  
22 a specific meaning to you?

23 A. Yes.

24 Q. How do you use the term "opioid"?

25 A. It covers all -- the difference between

1     opiate and opioid is purely naturally occurring versus  
2     synthetic, so opioid covers all opiates and opioids.

3           Q.   Did you make any distinction as you use it in  
4     any of your professional writings between prescription  
5     opioids versus illicit opioids, including street drugs  
6     like heroin?

7           A.   They all fall your opioids.

8           Q.   And is that how you have used the term in  
9     your expert report in this case?

10          A.   Yes.

11          Q.   So, have you been an expert witness in other  
12     cases before this one?

13          A.   Yes.

14          Q.   And have those been mostly medical  
15     malpractice cases?

16          A.   Correct.

17          Q.   Do you have any questions about what it means  
18     to be an expert witness?

19          A.   No.

20          Q.   Do you understand that when you did a report  
21     and you dated it and signed it, that it was to include  
22     all of the opinions that you would intend to offer at  
23     trial?

24          A.   Yes.

25          Q.   Did you attempt to do so in the expert report

1 for this case?

2 A. Yes.

3 Q. Did you attempt to set forth both opinions  
4 that would be harmful for the plaintiffs' case and  
5 helpful for the plaintiffs' case?

6 MS. KEARSE: Object to form.

7 A. I guess I don't understand what you're  
8 asking.

9 Q. Well, as an expert witness when you evaluate  
10 whatever your subject matter is that is within your  
11 area of expertise, do you attempt to set -- set forth  
12 in your report the opinions that you have regardless  
13 of whether they're good or bad for the party retaining  
14 you?

15 A. Correct.

16 Q. And in this case, did you also set forth all  
17 of the materials that you considered in forming your  
18 opinions?

19 A. Yes.

20 Q. Okay. And since you did your report, have  
21 you formed any new opinions relevant to this case?

22 A. No.

23 Q. Have you looked at any additional materials  
24 beyond what is disclosed in connection with your March  
25 25, 2019 report?

1           A. I continue to review articles and  
2     publications as they come through, so it is hard to  
3     say if anything that I reviewed is something that  
4     you're going to ask about, I guess.

5           Q. Well, I'm not so focused about what I'm going  
6     to ask about.

7           A. Yeah.

8           Q. I'm more interested in whether there is any  
9     literature that has come out in the last, let's say,  
10    four weeks that you think is pertinent to the subject  
11    matter that we are discussing here today, or you  
12    anticipate we are discussing today consistent with the  
13    scope of your report?

14          A. No.

15          Q. Have you had any additional research efforts,  
16    whether published or not, that pertain to the subject  
17    matter that is addressed in your expert report in this  
18    case?

19          A. Can you repeat that one more time, please?

20          Q. Sure. Why don't I do it this way. We got  
21    with your report a copy of your CV.

22          A. Uh-huh.

23          Q. And plaintiffs' counsel was nice enough  
24    before the deposition got started to give us an  
25    updated version of your CV.

1           A.   Correct.

2           Q.   My understanding is that the nature of the  
3   update is to list some additional publications,  
4   including maybe some things that were previously  
5   published only in abstract form and are now full  
6   publications.

7           A.   Correct, those were updated to dates.

8           Q.   Is there any other change to your CV compared  
9   to the one we got?

10          A.   No.

11          Q.   So other than your own literature, is there  
12   anything that you have reviewed over the last four  
13   weeks that relates to the issue of neonatal abstinence  
14   syndrome or any of the other areas addressed in your  
15   expert report in this case?

16          A.   No.

17          Q.   In terms of your personal experience over the  
18   last four weeks, have you continued to treat patients  
19   and do the same sort of general responsibilities that  
20   you had before you signed your expert report?

21          A.   Yes.

22          Q.   Is there anything in your mind, whether it is  
23   material you considered or some new opinion you  
24   formed, that requires you to supplement or amend your  
25   report in any way?

1 A. No.

2 Q. So in other words, the report that we got  
3 about a month ago is still your report that includes  
4 all of your opinions, and the disclosures that went  
5 with it are accurate and complete, correct?

6 A. Correct.

7 Q. In connection with forming your expert  
8 opinions in this case, were there materials that you  
9 hoped to review or issues you hoped to address that  
10 you weren't able to because of time constraints or not  
11 getting information you wanted or anything like  
12 that?

13 A. No.

14 Q. Do you have ongoing analyses in any of your  
15 ongoing research that you are aware of the results of  
16 them that but they haven't been yet published or  
17 disclosed publicly?

18 A. Yes.

19 Q. Is there any of that that you intend to rely  
20 on for your opinions in this case?

21 A. Yeah.

22 Q. So can you tell me what you're talking about  
23 then?

24 A. I have three papers that are pending or under  
25 review currently.

1 Q. And are those all related to the work through  
2 the Ohio Perinatal Quality Collaborative?

3 A. One of them is.

4 Q. And I don't know if you have these limits,  
5 but sometimes researchers are unwilling to disclose  
6 the subject matter of their research before it is  
7 published.

8 Do you feel you're bound by such  
9 limitation?

10 A. I would feel comfortable discussing the  
11 topics, but not the actual results until they are  
12 published because that could interfere with getting  
13 published.

14 Q. Like an Ingelfinger rule sort of issue,  
15 right?

16 A. I don't know what that is.

17 Q. Is any of the literature that you are in the  
18 process of getting published going to change your  
19 opinions in terms of what you recommend as a program  
20 to be implemented or changed for Cuyahoga or Summit  
21 County going forward?

22 A. Possibly.

23 Q. So subject to the limits you believe you have  
24 and based on the information that you have currently  
25 on those three papers, can you walk through them one

1 at a time and tell me --

2 A. Sure.

3 Q. -- what the subject matter is of the first  
4 paper?

5 A. So the first paper is regarding the OPQC  
6 summary report. And it is really just summarizing --

7 MS. HELLER-TOIG: I'm -- this is Elly  
8 Heller-Toig. I cannot hear him.

9 MR. BOECK: Agreed. This is Chris Boeck on  
10 behalf of Henry Schein. I cannot hear the witness.

11 MS. HELLER-TOIG: And also, the video is  
12 gone. I don't know if anyone else is experiencing  
13 that.

14 MR. BOECK: Same here.

15 MR. ALEXANDER: I would suggest we go off the  
16 record for like two minutes and try to fix it. I  
17 don't know that we've gotten the appearances of  
18 anybody on the phone yet, other than the individual  
19 who said he represented the Schein defendant.

20 THE REPORTER: They were sent to me  
21 yesterday.

22 MR. ALEXANDER: Okay.

23 MS. HELLER-TOIG: This is Elly Heller-Toig.  
24 We represent HBC Service Company from Marcus &  
25 Shapira.



1 MR. ALEXANDER: I think we need agreement of  
2 plaintiffs' counsel to go off the record under the  
3 federal rules.

4 MS. KEARSE: Oh, I'm sorry. I nodded yes.  
5 I'm fine with that. Yes.

6 THE VIDEOGRAPHER: We are now going off  
7 record. The time is 9:32.

8 (Off-the-record discussion.)

9 THE VIDEOGRAPHER: We are now back on record.  
10 The time is 9:43.

11 MR. ALEXANDER: Hopefully, we fixed some of  
12 our technical difficulties.

13 BY MR. ALEXANDER:

14 Q. We had a pending question before the little  
15 break there, and you are in the middle of your answer,  
16 Dr. Wexelblatt.

17 Just to orient everybody, I'm going to have  
18 the last question read back by the court reporter, and  
19 then if you could start your answer concerning the  
20 additional research papers in progress that you were  
21 discussing.

22 (Previous questions/answers were read back by  
23 the court reporter commencing as follows:

24 Question: So subject to the limits you  
25 believe you have and based on the information that you

1 have currently on those three papers, can you walk  
2 through them one at a time and tell me --

3 Answer: Sure.

4 Question -- what the subject matter is of  
5 the first paper?

6 Answer: So the first paper is regarding the  
7 OPGC summary report. And it is really just  
8 summarizing...)

9 THE WITNESS: So the first paper is regarding  
10 the OPQC --

11 THE REPORTER: Oh, sorry.

12 THE WITNESS: -- paper, and it's just a  
13 summary of our findings after completing our  
14 enrollment, which ended up being 9,000 -- over 9,000  
15 patients.

16 The second paper --

17 Q. Can I pause you there on the first paper?

18 A. Correct.

19 Q. So that has been submitted for publication to  
20 a journal, correct?

21 A. Correct.

22 Q. Has that been accepted for publication?

23 A. It is under review.

24 Q. And which of your prior papers is this  
25 essentially providing follow-up data on? If you can

1 do it by citation or --

2 A. It would be the one that starts with Walsh,  
3 and it talks about statewide collaborative.

4 Q. Okay.

5 A. And I think I'm the third author -- third  
6 author on that paper.

7 Q. If you go on to the second pending paper.

8 A. That is regarding visual findings in infants  
9 in our high-risk NAS follow-up clinic. And that is a  
10 follow-up of our abstract that is listed on the paper  
11 that is being presented this weekend at Pediatric  
12 Academic Society meeting.

13 Q. Okay.

14 A. And it's listing or showing the incidence of  
15 visual disturbances at six months of infants that are  
16 treated for NAS.

17 Q. Is that strabismus or something else?

18 A. Correct.

19 Q. Any other end points in that study besides  
20 strabismus?

21 A. Those that went on to need surgery for  
22 correction.

23 Q. Okay. And there is some prior literature on  
24 that subject, correct --

25 A. Correct.

1 Q. -- that you cited already?

2 A. Uh-huh.

3 And then the third paper is regarding the  
4 rates of Hepatitis C in opioid-exposed infants.

5 Q. Does that just look at incidence or does it  
6 talk about treatment?

7 A. It is talking about -- it's regarding  
8 identification and correct testing of infants at the  
9 correct time, and it is looking at the cascade of  
10 underreported cases.

11 Q. So, when we got started I didn't really go  
12 over the ground rules of deposition because you're  
13 close enough to the court reporter that she might kick  
14 you if you, you know, run afoul of some unspoken  
15 rules. I'm going to speak a couple of them just to  
16 make it a little smoother as we go forward.

17 Even though you're on video, it is important  
18 that people not talk over one another because that  
19 makes the court reporter's job hard, and we want to  
20 make sure that the written transcript at the end of  
21 the day accurately reflects what you know and think.

22 So, if you could do your best to not start  
23 your answer until I finish my question, I am sure I'll  
24 do the same on the other end.

25 Does that make sense?

1           A.   Yes.

2           Q.   If you need to take a break at any time, we  
3   will take a break.  If you don't understand my  
4   question, let me know.  I'll try to fix it and make it  
5   intelligible.

6           Does that make sense?

7           A.   Yes.

8           Q.   If there is an objection, as there has been  
9   one or two so far, that is just as to the form.  If  
10   you understand the question, if you can answer it, go  
11   ahead and do so anyway.  If there is an instruction  
12   not to answer, I'm not sure what that would be on, but  
13   if there is, that is between you and plaintiffs'  
14   counsel.

15           If you need to take a break to confer about  
16   any issue in the deposition, please try not to do so  
17   unless there is no pending question -- double  
18   negative.  Try not to do it when there is a pending  
19   question unless the conferral relates to whether  
20   you're allowed to answer the question.

21           Does that all make sense?

22           A.   Yes.

23           Q.   Do you have any other questions for me about  
24   the deposition procedure?

25           A.   No.

1 Q. And you've been deposed a couple of times  
2 before, correct?

3 A. Correct.

4 Q. Have you ever testified at trial?

5 A. Once.

6 Q. Was that in connection with a case where you  
7 were an expert witness or some other type of case?

8 A. Expert witness.

9 Q. Have you ever testified in a case where you  
10 were a party?

11 A. No.

12 Q. Have you ever been sued for medical  
13 malpractice?

14 A. No.

15 Q. That's lucky. Right?

16 MS. KEARSE: Object to form.

17 BY MR. ALEXANDER:

18 Q. So, let's go back to where we are on these  
19 papers.

20 So these are three papers that are in the  
21 process of trying to get published, correct?

22 A. Correct.

23 Q. You said the first one is review -- in the  
24 middle of peer review. The second one about visual  
25 issues in neonatal abstinence syndrome of children.

1           Is that pending publication, has that been  
2   accepted for publication?

3           A.   It has not been accepted.  It's -- they're  
4   all under review.

5           Q.   Do you have any other ongoing research where  
6   you're aware of the results and they have not yet been  
7   published and you intend to rely on them in connection  
8   with anything about your testimony for this case?

9           A.   Not outside those three papers.

10          Q.   And without giving away anything that might  
11   jeopardize the publication of the first paper, the  
12   follow-up on the Walsh paper, are the results  
13   dramatically different than what had been published  
14   before in terms of any of the metrics that you are  
15   tracking?

16          A.   No.

17          Q.   In the papers that you have been doing  
18   through the OPQC, the Ohio Perinatal Quality  
19   Collaborative, there is sometimes data presented by  
20   regional, Region, 1, 2, 3, 4, 5 and 6, correct?

21          A.   Correct.

22          Q.   And some of the participating hospitals in  
23   each of those regions are in Cuyahoga County and some  
24   are in Summit County, correct?

25          A.   Correct.

1 Q. Do you know which number region Cuyahoga  
2 is?

3 A. When we publish it and when we started the  
4 collaborative, we agreed to keep them confidential.

5 Q. Okay. I mean, are you blinded from that as  
6 far as you're writing up the papers and evaluating the  
7 data?

8 A. I am not blinded.

9 Q. So you do know which one is Cuyahoga and  
10 which one is Summit, correct?

11 A. Correct.

12 Q. And are you willing to say that here today?

13 A. No.

14 Q. Do you rely on anything specific to Cuyahoga  
15 and Summit County from those papers where the  
16 particular region is applicable to Cuyahoga and Summit  
17 is not included in the final publications in offering  
18 any of your opinions in this case?

19 A. No.

20 Q. So let me just go back, because part of the  
21 issue here, as you have said, is you've been asked to  
22 offer opinions relating to neonatal abstinence  
23 syndrome and impact on Cuyahoga and Summit Counties,  
24 correct?

25 A. Correct.



1 Q. Okay. And you've never worked in Cuyahoga or  
2 Summit County, correct?

3 A. Not directly seeing patients.

4 Q. And you don't have any positions with either  
5 of those counties in terms of governmental positions  
6 or adjunct positions, correct?

7 A. Correct, I do not.

8 Q. Are you relying on any information that you  
9 gained that is specific to Cuyahoga or Summit County  
10 through any of the work that you have done through the  
11 OPQC?

12 A. Working in collaboration with the leaders in  
13 those regions, I have an understanding of what is  
14 happening through OPQC.

15 Q. And do you intend to offer any testimony at  
16 trial based upon that understanding that you have  
17 gathered through your work through OPQC that is not  
18 reflected in the published papers that hide which  
19 region is which?

20 MS. KEARSE: Object to form.

21 A. No.

22 Q. In connection with your opinions on -- that  
23 you are going to offer in this case, have you talked  
24 to anybody for Cuyahoga or Summit County based upon  
25 their particular experiences relating to neonatal

1     abstinence syndrome or maternal use of opioids or  
2     opiates?

3             A.   We work in direct collaboration with, like,  
4     leaders from each of these -- the main six regions  
5     that we have, our six children hospitals.  And so  
6     there is a representative from each of those counties  
7     in this collaboration.

8             Q.   Okay.  So in connection with your opinions in  
9     this case, so, in your report, you disclose that you  
10    did literature review, you relied on your experience,  
11    you, you know, generally thought about the issues that  
12    you have been living for a decade or so now.

13            So what I'm asking is:  Specific to the work  
14    that you did to prepare your opinions and -- and set  
15    them out in a report for this case so we would know  
16    what you were going to talk about and what you relied  
17    on, did you actually talk to anybody from Cuyahoga or  
18    Summit County about any of these issues?

19            A.   Not about writing up this report.

20            Q.   Did you talk to anybody from Cuyahoga County  
21    -- take it one-by-one.

22            In connection with forming your opinions for  
23    this case, did you talk to anybody from Cuyahoga  
24    County about their experiences relating to -- did you  
25    call it NAS?  Is that the abbreviation you would

1 use?

2 A. Uh-huh.

3 Q. -- NAS or anything related to maternal use of  
4 opioids?

5 A. So I'm in connection with people at -- on  
6 monthly phone calls that are in that region.

7 Q. And do you intend to rely on any of that  
8 information for any of the testimony that you give in  
9 this case?

10 A. It is all a part of it, correct.

11 Q. And who have you talked to from Cuyahoga  
12 County?

13 A. So on our monthly calls, Susan Ford is out of  
14 Rainbow Babies. Michelle Walsh is part of Rainbow  
15 Babies. And Jay Iams is O.B. director -- I'm sorry,  
16 he's not in Cuyahoga County. I take that back.

17 Q. Okay. So, the first two individuals --

18 A. Yes, those two reside in Cuyahoga County.

19 Q. I'm not so focused on where they reside. I'm  
20 focused on where they work, though.

21 A. Correct, that's where they work.

22 Q. Okay. And so, are there specific  
23 conversations or information that you have gained from  
24 your communications with these two individuals who  
25 were coauthors on your papers that you intend to rely

1 on in offering any of your testimony at trial?

2 A. It is all a part of the OPQC project, so we  
3 talk about there's different models in different parts  
4 of the state. So if that is what you're referring to,  
5 then I guess it is specific to that.

6 Q. And when you say specific models, do you mean  
7 in terms of what Cuyahoga County is already doing to  
8 address these sorts of issues?

9 A. Correct.

10 Q. And over time, as I understand it, part of  
11 what OPQC has done is try to standardize some of the  
12 models even though there are regional differences.

13 Is that a fair statement?

14 A. That is.

15 Q. Okay. So, what the Cuyahoga model was at a  
16 given point in time may not be what it is now because  
17 it has been updated in various ways?

18 A. Exactly.

19 Q. And have you talked to these two coauthors  
20 from Cuyahoga County about when it was that they first  
21 started seeing a need to do more, to do different  
22 things, to have increased efforts to try to address  
23 issues of NAS or other public health impacts of  
24 increasing maternal opioid use?

25 A. Did you ask when or if?

1 Q. Did you talk to them about the issue of when?

2 A. Yes.

3 Q. I had both of those words in there.

4 A. Yes.

5 Q. And did you gain an impression from them that  
6 this was something that they had been seeing for many  
7 years before you actually started collaborating in the  
8 collaborative?

9 MS. KEARSE: Object to form.

10 A. The reason we started the collaborative was  
11 based on the increase of incidence.

12 Q. And so the collaborative itself started back  
13 in 2007, correct?

14 MS. KEARSE: Object to form.

15 Q. The Ohio Perinatal Quality Collaborative  
16 started in 2007?

17 A. I'm not exactly sure when it was first  
18 initiated.

19 Q. And sometime after that, it set up a project  
20 on neonatal abstinence syndrome, correct?

21 A. Correct.

22 Q. Do you know when that project started?

23 A. 2014.

24 Q. And the way it works -- have you been  
25 involved with other projects with OPQC?

1 A. No -- well, yes.

2 Q. At any again time they may have multiple  
3 different projects that are kind of where they focus  
4 their efforts and then over time they may have some  
5 follow-up or monitoring of them over time, correct?

6 A. Correct.

7 Q. So, before a project like the neonatal  
8 abstinence syndrome project gets started, there is  
9 some ramp-up time, correct?

10 A. Yes.

11 MS. KEARSE: Object to form.

12 Q. There is talking about basically where the  
13 efforts are going to be focused, where money might be  
14 given, who is going to participate, and that sort of  
15 thing?

16 MS. KEARSE: Object to form.

17 Q. Correct?

18 A. Yes.

19 Q. Do you know when the talk about initiating a  
20 neonatal abstinence syndrome project through the Ohio  
21 Perinatal Quality Collaborative started?

22 A. I think it happened after our first  
23 publication in 2000 -- well, after our results were  
24 finished in our Ohio Children's Hospital  
25 Collaborative, research collaborative, which those --

1 our initial results were compiled in 2013. And then  
2 that's when the discussion was to spread it to OPQC  
3 outside of OCHA, O-C-H-A, Ohio Children's Hospital  
4 Research Association.

5 Q. So for the Ohio Children's Hospital Research  
6 Association --

7 A. Yeah.

8 Q. I'm sorry. It's Ohio Children's Hospital  
9 Association?

10 A. Yeah.

11 Q. There's no "R" in there.

12 A. Okay.

13 Q. That's a long-standing entity that has been  
14 around for way longer -- it's been since 2007,  
15 correct?

16 A. I'm not sure.

17 Q. Okay. How long have you been involved with  
18 that entity?

19 A. 2012.

20 Q. And how long have you been involved with the  
21 OPQC?

22 A. 2014 directly as a faculty member; however, I  
23 did work on their 39-week gestation project at one of  
24 the hospitals prior to that.

25 Q. So, do you recall when it was that you

1 personally first had started having an interest in the  
2 need to do more to address rising rates of neonatal  
3 abstinence syndrome in the Cincinnati area or any  
4 other health impacts of increasing maternal use or use  
5 by women of childbearing age of opioids or opiates?

6 MS. KEARSE: Object to form.

7 A. Probably around 2010 or '11, right before we  
8 started the collaborative.

9 Q. And so -- so you started some research  
10 efforts with colleagues down here starting around that  
11 time, and then eventually it wasn't statewide; is that  
12 a fair statement?

13 A. No.

14 Q. Give me the accurate statement then of --

15 A. We had been addressing the problem locally,  
16 then we really didn't want to make any significant  
17 changes until we had data and research to support it.  
18 And that's what we were able to obtain through OCHA's  
19 first 18 months.

20 Q. And so we talked about the two individuals  
21 you ultimately have discussed this with from Cuyahoga  
22 County, correct?

23 A. Uh-huh.

24 Q. Your coauthors?

25 A. Yes.



1           Q. When you finally were kind of connected with  
2   them for statewide research efforts and quality  
3   improvement efforts through OPQC, did you find that  
4   they had had a parallel track of having local interest  
5   and electronic efforts for some period of time before  
6   you started talking about it?

7           MS. KEARSE: Object to form.

8           A. I know they had been working on it.

9           Q. Do you have an idea of how long they had been  
10   working on it?

11          A. I don't.

12          Q. So, let's then do the other county, Summit  
13   County.

14                 Have you had communications about essentially  
15   what efforts have been going on in Summit County, for  
16   how long, how they have been going, with anybody who  
17   actually works in Summit County that you intend to  
18   rely on for your opinions in this case?

19          A. Yeah. So one of our coauthors, Jennifer  
20   Grow, is out of Summit County.

21          Q. Is that Dr. Grow?

22          A. Correct.

23          Q. So this is easy because it's just one person.

24                 For Dr. Grow, when did you first start  
25   talking to her about any of these issues?

1 A. 2012.

2 Q. Okay. And in 2012, was that through OCHA or  
3 OPQC?

4 A. OCHA.

5 Q. All right. Did you gain an understanding  
6 from talking to Dr. Grow about how long there had been  
7 efforts or interest in Summit County of doing more to  
8 address rising rates of NAS and other health impacts  
9 of maternal use of opioids or opiates?

10 MS. KEARSE: Object to form.

11 A. I would not know the exact time, but I think  
12 it is similar, within the year prior.

13 Q. So, your impression is that this had been  
14 something that people who specialized in this area in  
15 Summit County had been aware that this was a rising  
16 issue and needed essentially more effort to make for  
17 better outcomes in the children and the mothers in  
18 Summit County since at least 2011; is that correct?

19 MS. KEARSE: Object to form.

20 A. Correct.

21 Q. And for Cuyahoga County, you think it is a  
22 similar time period?

23 A. Correct.

24 Q. Ultimately, do you think that the current  
25 programs that have been developed through your work

1 with OPQC have the ability to help improve outcomes  
2 for children and mothers affected by the maternal  
3 abuse of opioids or opiates?

4 A. Yes.

5 Q. And do you think that these are efforts that  
6 over time, as they have kind of evolved both in terms  
7 of the regional work you've done here and then the  
8 work done in other regions across the state, that  
9 those also had a benefit over the last several  
10 years?

11 A. Yes.

12 Q. Is it your view that if these product --  
13 these projects had been initiated kind of intensely  
14 and statewide, or at least in Cuyahoga and Summit  
15 County back in 2011 that things would be better off  
16 than they are now in terms of children who have been  
17 affected by NAS and other health impacts of maternal  
18 abuse of opioids and opiates?

19 MS. KEARSE: Object to form. Calls for  
20 speculation.

21 A. I would have no idea. I would have to -- how  
22 to say what would happen if we did anything in the  
23 past that would affect the future.

24 Q. Well, I'm talking about as of now. So, right  
25 now, in Cincinnati, where you work -- at the hospitals

1     where you work and where you have some idea into or  
2     some insight into the programs that have been  
3     placed -- do you think that they're doing a better job  
4     than they were before you started these quality  
5     control efforts, these development of standardized  
6     protocols?

7             MS. KEARSE: Object to form.

8             Q. Correct?

9             A. Yes, we have made improvements.

10            Q. Improvements in terms of the outcomes of the  
11    NAS children, that's one way you're counting an  
12    improvement, correct?

13            A. That is correct.

14            Q. Okay. And so some of the measures of  
15    improvement might be that you reduce the hospital  
16    stay, you reduce the total time on treatment with  
17    opioids as part of medically assisted therapy,  
18    correct?

19            MS. KEARSE: Object to form.

20            A. So we don't give MAT for infants. We treat  
21    withdrawal. So that's -- just a nuance.

22            And we also have been measuring as part of  
23    our MOMS Project with OPQC, by implementing  
24    projects. We have been showing to have improved in  
25    MAT adherence, behavioral therapy also for the

1 mothers.

2 Q. Okay. So let's break it up because I was  
3 going to ask about the offspring, the children first.

4 A. Okay.

5 Q. So what are the measures that you think are  
6 appropriate to track in terms of improvements? So we  
7 talked about average hospital stay at the time of  
8 delivery, correct? That's one?

9 A. Average length of stay, correct.

10 Q. And what else?

11 A. Days of opioid treatment, percent that are  
12 needing pharmacologic treatment. And then that would  
13 give you another measure, which we are now starting to  
14 show in our paper that is pending, all babies that are  
15 opioid exposed average length when you combined all of  
16 them together.

17 Q. And are you also tracking through any of this  
18 the cost of hospital stays in the perinatal setting?

19 A. Not a part of this project.

20 Q. And that is something that is discussed in  
21 some of the published papers, right?

22 A. Correct.

23 Q. That, in general, taking care of a NAS baby  
24 in the hospital costs more than taking care of an  
25 average baby because of longer average stays, medical

1 therapy, things like that?

2 A. Correct.

3 Q. I mean, pharmacotherapy, among other things,  
4 correct?

5 A. Correct.

6 Q. And so has there been any kind of tracking in  
7 terms of success of driving down costs?

8 A. We haven't measured it directly in any of our  
9 publications. They have been estimates -- estimates  
10 based on the average length of stay on statewide  
11 data.

12 Q. So like the periodic presentations that you  
13 do through OPQC, we have some of your PowerPoints,  
14 some of them identified with your report.

15 Those do track some of the metrics that you  
16 are talking about, correct?

17 A. Yes, they do.

18 Q. And so you have statewide information where  
19 you talk about that there is actually savings in  
20 healthcare dollars, regardless of who pays them, by  
21 the improvements that you are talking about,  
22 correct?

23 A. Yep.

24 Q. So, if these measures had been initiated  
25 earlier and you were able to drive down costs -- I'm

1     sorry, drive down average length of stay, length of  
2     opioid treatment, and some of these other metrics, you  
3     expect that there would have been even greater cost  
4     savings over time?

5             MS. KEARSE: Object to form.

6             A. We had to learn what worked to get to that  
7     point. So if we implement what we know now, then  
8     yes.

9             Q. And so the data, that -- since you  
10    implemented the standard protocol, shows there has  
11    been a reduction in most of these metrics over time;  
12    not necessarily in a linear fashion, but overall it's  
13    gone a little bit up and down, but all of these have  
14    improved over the now, what, like seven years or so  
15    since you initiated a standard protocol?

16            A. Yeah.

17            MS. KEARSE: Object to form.

18            Q. And that's what you hoped for, right?

19            A. Exactly.

20            Q. So even though you haven't necessarily  
21    tracked it in a dollar basis at any given time which  
22    protocol saved what money, the earlier the protocol  
23    was started, the earlier you get to a better or more  
24    refined protocol, the better outcomes you get and the  
25    more healthcare dollars you save, correct?

1 MS. KEARSE: Object to form.

2 A. Yeah. If you can decrease the length of  
3 stay, then you've obviously impacted the dollars.

4 Q. And some of the other things have potential  
5 long-term benefits, too.

6 Your belief is that by having early  
7 appropriate treatment of the NAS offspring, you hope  
8 to be able to improve their long-term outcomes, too,  
9 right?

10 A. Yes.

11 Q. That would include like, less need for  
12 behavioral intervention, less chance of long-term  
13 addiction, less chance of other potential, at least  
14 theoretical, complications in an NAS child, correct?

15 MS. KEARSE: Object to form.

16 A. We would want to improve all of those  
17 things.

18 Q. Are there other specific -- I mean, we were  
19 -- it is my language, so I'm being a little general  
20 and hopefully we can have a little more specific.

21 So are there other health outcomes that might  
22 require medical or social services interventions or  
23 even educational interventions that you hope to  
24 improve by the work that you are doing in terms of  
25 standardized protocols for treatment of NAS



1 children?

2 A. So it is a very evolving arena, and so when  
3 we are discussing some of the long-term outcomes,  
4 that's what we are trying to learn in our NAS  
5 high-risk follow-up clinic.

6 And that's where we have sort of run into  
7 finding this visual disturbances, torticollis, other  
8 musculoskeletal issues that we are finding as we  
9 continue to look into this group.

10 Q. So a couple of things there. The torticollis  
11 is like a kind of twisting of the neck, a stiffness of  
12 the neck?

13 A. That's a good layman's description.

14 Q. And that tends to resolve on its own?

15 A. With physical therapy. It usually requires  
16 physical therapy at this age.

17 Q. It is a time limited phenomenon, it's not a  
18 life-long issue?

19 A. That's correct.

20 Q. And the strabismus, some people require --  
21 understand that this is an issue basically of the eye,  
22 their ability to focus together in a -- like a  
23 stereoscopic fashion?

24 A. So a layman's version would be lazy eye.

25 So what we try to do, there is multiple

1 interventions you can try to do to prevent surgery to  
2 correct. And so there is patching or drops that you  
3 would do on the good eye, so they would then try to  
4 match each other so the pathways are there that you  
5 wouldn't need corrective surgery if it doesn't -- if  
6 it goes past too long of a time.

7 Q. And is it the minority of cases with  
8 strabismus that need corrective surgery, in your  
9 experience?

10 A. That's what we are looking into and  
11 publishing, getting into it.

12 Q. That data is not out yet?

13 A. Correct.

14 Q. From the larger literature on strabismus in  
15 children who have maternal exposure to drugs, and I  
16 think it has been tracked with various drugs over  
17 decades, there is some information that the minority  
18 of them actually go on to have surgery, correct?

19 MS. KEARSE: Object to form.

20 A. Correct.

21 Q. And those that don't may just need glasses?

22 A. Unknown.

23 Q. So, your clinic -- I think you reference this  
24 in your report -- is, as far as you know, the only  
25 clinic that's doing kind of longitudinal following of

1 the NAS children; is that correct?

2 A. I'm aware of a couple other in the country.

3 Q. Okay. So from any of this long-term  
4 follow-up at your clinic, is there any data being  
5 generated that looks at long-term outcomes, the  
6 frequency of requiring additional interventions,  
7 healthcare costs or other additional costs associated  
8 with any of these issues beyond what you have already  
9 identified as pending publication?

10 A. It is ongoing, correct.

11 Q. Okay. So are there other research efforts  
12 that you are aware of where you have data in your head  
13 relating to long-term health implications of being  
14 born with NAS --

15 MS. KEARSE: Objection.

16 Q. -- that you intend to testify about at trial  
17 but we don't know because they haven't been  
18 published?

19 MS. KEARSE: Object to form.

20 A. Not that I haven't talked about in those  
21 three papers.

22 Q. Okay. The general consensus is there is not  
23 sufficient scientific evidence to say that there are  
24 actually long-term detriments of NAS in terms of  
25 deviating from the expected norm for educational

1 requirements, behavioral requirements, and the other  
2 metrics that you are talking about when you -- when  
3 you account for things like socioeconomic status, the  
4 number of parents in the household, and other just  
5 kind of social factors that are typically tracked in  
6 those states.

7 Would you agree with that?

8 MS. KEARSE: Object to form. Object to form,  
9 and I'm objecting to the questions of who is  
10 testifying here, Counsel.

11 So, if you have a question about his  
12 opinions, ask him his opinion, I think you are  
13 actually putting testimony in the record on that too,  
14 of your opinions, so...

15 MR. ALEXANDER: That's an improper objection  
16 under the rules for this court.

17 Q. But if you understand the question, go ahead,  
18 please, Doctor.

19 A. I wouldn't agree completely with that  
20 statement.

21 Q. Is there any specific area where you believe  
22 there is a scientific consensus that there is a  
23 long-term detriment requiring additional medical,  
24 social or educational intervention long-term past,  
25 let's say, six months, for an NAS baby?

1 A. Yes.

2 Q. Okay. What area?

3 A. We have publication that looks at Bayley  
4 scores, which is a developmental test that's done at  
5 two years of age that showed a decrease in Bayley  
6 scores to those that were -- infants that were  
7 diagnosed with NAS compared to the normative.

8 Q. That is one of your citations in your report,  
9 correct?

10 A. It is.

11 Q. And even though they're lower than the norms  
12 than the comparators of that study, they're still  
13 within the normal range, correct?

14 A. Their average is lower -- statistically lower  
15 than the norm. And then if you look at the range of  
16 low scores, then the third and fourth quartile is  
17 definitely out of the range.

18 Q. And we can get to that paper later.

19 A. Uh-huh.

20 Q. But one of the issues in this area of  
21 research, if you will, and there has been a lot of  
22 research over the decades relating to babies whose  
23 mothers used cocaine, specifically crack cocaine,  
24 while they were pregnant and other drugs over time.

25 Do you agree with me so far: There's been a

1 lot of research on the issue of whether basically  
2 being born to a mother who was using drugs has  
3 long-term health impacts that require additional  
4 interventions?

5 A. I agree with that.

6 Q. So one of the issues in this area of trying  
7 to do good research is trying to weed out all of the  
8 confounding factors that you might have in some child  
9 who is born in that setting, but is going to  
10 necessarily be raised with potential other problems,  
11 whether they be poverty, limited educational access,  
12 limited healthcare access, exposure to violence,  
13 trauma, increased abuse rates, all of those sorts of  
14 real-world considerations.

15 Those make it hard to do good research that  
16 pulls out whether the fact of birth with some sort of  
17 dependence has long-term impacts or the other things  
18 do, right?

19 MS. KEARSE: Object to form.

20 A. I disagree with that statement.

21 Q. Okay. What is wrong about it?

22 A. Our paper that we just got published looked  
23 at discrepancies of opioid-exposed infants, and our  
24 cohort that we matched them to that were opioid  
25 exposed were that 15,000 -- I think it was 14,900,

1 was based out of our primary care center inside  
2 Cincinnati Children's Hospital.

3 So this is an inner-city population, very  
4 high Medicaid population, so we didn't directly look  
5 at the SES specifically; but our assumption based on  
6 knowing what our population is that we were dealing  
7 with a very similar SES as those that were opioid  
8 exposed.

9 Q. So you used the abbreviation SES.

10 What does that mean?

11 A. Socioeconomic status.

12 Q. So in addition to socioeconomic status, there  
13 are other potential confounders, correct?

14 A. Correct.

15 Q. So one of the things you saw, if we are  
16 talking about the same paper, is that the children who  
17 were not living with their birth mother, the one who  
18 was abusing drugs while pregnant, but were living with  
19 a foster family, or an adoptive family, they didn't  
20 have the difference in Bayley scores, did they?

21 A. That's a different paper.

22 Q. Okay. So isn't that an issue for any of this  
23 research: That you have to look at whether they're  
24 still living with the mother versus living somewhere  
25 else?

1           A. The socioeconomic status that the baby is  
2     living in does have an impact on their long-term  
3     outcomes.

4           Q. So what -- what are all of the individual  
5     criteria that you would put in as being relevant to  
6     incidence of behavioral issues, how long until they  
7     speak, how long until -- you know, the -- the other  
8     metrics of educational and behavioral performance that  
9     are measured in your studies, what are the other  
10    socioeconomic criteria that matter other than income  
11    level?

12           MS. KEARSE: Object to form.

13           A. Maternal education. Stuff that we have  
14     talked about in our very first paper. We looked at  
15     maternal education. We looked at insurance type.  
16     That gives us an idea of the SES.

17           And those would have had the biggest --  
18     gestational age is another big impact.

19           Q. Okay. So in the paper that you are talking  
20     about, did you control for all of those?

21           A. No.

22           Q. Is there any paper that controls for all of  
23     the confounding factors that you think exist that  
24     shows that NAS birth status has long-term impacts on  
25     Bayley scores or some other measure of functionality



1 or education or social needs?

2 MS. KEARSE: Object to form.

3 A. That would be an impossible study to do.

4 Q. So no, there isn't one?

5 A. Correct.

6 Q. So let me just go back for a second because I  
7 want to make sure that we're on -- on the same page  
8 with this.

9 The data that is in your papers and in some  
10 of your presentation shows that about seven out of  
11 eight NAS babies diagnosed in Ohio since you've been  
12 tracking this since roughly 2011 are Medicaid,  
13 correct?

14 MS. KEARSE: Object to form.

15 Q. Meaning their mother's insurance type is  
16 Medicaid as opposed to private insurance or some other  
17 pay?

18 A. Roughly. That's a good rough estimate.

19 Q. 86.4 percent, something like that?

20 A. That seems very close, yes.

21 Q. So in Ohio, the percentage on Medicaid is  
22 less than half, correct?

23 A. I don't know exact number.

24 Q. It is in the same charts in your paper -- in  
25 your report?

1 A. Okay.

2 MS. KEARSE: Counsel --

3 Q. Are you aware of that?

4 MS. KEARSE: Counsel, if you want to refer to  
5 a paper or something in his report --

6 MR. ALEXANDER: I will when we need to.

7 A. I wouldn't know the exact number off the top  
8 of my head.

9 Q. Do you know if it's more or less than half.

10 A. It would probably be right around there, but  
11 I would be -- not knowing exactly the number.

12 Q. So does -- if it is about half, and the  
13 percentage of NAS babies whose mothers are on Medicaid  
14 is close to 90 percent, does that tell you anything  
15 about the impact of socioeconomic status on the  
16 incidence of NAS?

17 MS. KEARSE: Object to form.

18 A. It would imply that there is a higher impact  
19 in the Medicaid population.

20 Q. Have you identified other socioeconomic  
21 drivers of the likelihood of being born with NAS other  
22 than the fact of maternal drug use?

23 A. Caucasian has been a factor.

24 Q. Anything else?

25 A. Not that I can think of off the top of my

1 head.

2 Q. So I know you started by saying that your  
3 studies and your series of studies through OPQC have  
4 identified certain things, like insurance status, as  
5 drivers of -- or essentially socioeconomic status that  
6 you would be tracking in the research, correct?

7 A. We track insurance type as an indicator.

8 Q. What are the other indicators that you are  
9 aware of that you don't track?

10 A. Maternal education is something that we  
11 usually don't track after that first paper.

12 Q. Why not?

13 A. It was just too hard to get all of that data  
14 once we expanded our numbers.

15 Q. And I -- by none of these questions do I mean  
16 to minimize anything about the plight of a child who  
17 has these sorts of issues or maternal drug use.

18 But this is a matter of: You-guys have to  
19 decide your research parameters, right? You have to  
20 figure out what you can track and what you don't?

21 MS. KEARSE: Object to form.

22 A. We come up with a list of things we are going  
23 to track and -- before -- in our methodology before we  
24 go ahead and start any research project.

25 Q. And you try to track things that you think

1 are important to doing the research project in a  
2 serious and reliable way, correct?

3 A. Yes.

4 Q. Okay. So part of the reason that you would  
5 track like insurance status is because the -- there  
6 are associations of poverty itself to some of the same  
7 things that you would be tracking, like the incidence  
8 of educational deficits, increased behavioral  
9 problems, et cetera, correct?

10 A. That's an assumption.

11 Q. Okay. I mean, is there literature on that?

12 A. Yes.

13 Q. And you think the literature shows that there  
14 is an association that there is a higher likelihood in  
15 somebody who is on Medicaid versus somebody with  
16 private insurance that their offspring will have  
17 educational deficits compared to the norm?

18 A. I don't think that's a good statement that I  
19 would state.

20 Q. How would you say it?

21 A. I would state you have to look at each  
22 individual on the individual basis, so if the -- I  
23 wouldn't want to categorize somebody just because they  
24 have Medicaid that they're not going to have an  
25 educational outcome of a normal person.

1           Q. Statistically speaking, based upon broad  
2     population, is there some association between economic  
3     status and these sorts of educational metrics of how  
4     soon somebody speaks or reads or how they do on  
5     standardized scores?

6           A. I'm not aware of it.

7           Q. So why do you track Medicaid status?

8           A. We know that the burden -- NAS -- the  
9     incidence of NAS is higher in women that are falling  
10    into the category of Caucasian and those on  
11    Medicaid.

12          Q. So are you aware of other factors that affect  
13    the incidence in children of behavioral issues,  
14    educational deficits, or any of the other sorts of  
15    potential long-term impacts that you are actually  
16    studying?

17           MS. KEARSE: Object to form.

18          A. I guess I don't know what you're asking  
19    here.

20          Q. Sure. It was -- it was a horrendous  
21    question. I'll try to fix it.

22           So in your long-term studies at your clinic,  
23    one of the things that you are tracking and that maybe  
24    will do research on in the future will be things like  
25    you said Bayley scores. You also have some metrics of

1     like self-reported behavioral issues. You have how  
2     early it is that the child, like, speaks, correct?

3             Those are some of them?

4             A. Yes, and utilization of resources in the  
5     medical community.

6             Q. What are the other indicators of educational  
7     or behavioral or medical needs that you are  
8     tracking?

9             A. Utilization of speech, OT, PT, are the main  
10    ones, behavioral therapy and then subspecialties.

11            Q. Is it your belief that all of the things that  
12    you are tracking are more likely to be increased;  
13    meaning there is a higher likelihood of a deficit in  
14    one of these areas or a need for additional services  
15    in the Medicaid population versus the non-Medicaid  
16    population?

17            MS. KEARSE: Object to form.

18            A. So that's what we discuss in our last paper,  
19    discrepancies where we were able to compare it to the PPC  
20    or primary care sender in our hospital, which was a  
21    very high Medicaid. And we did find a difference in  
22    those that were opioid exposed compared to those that  
23    were not.

24            Q. That wasn't my question, though. My question  
25    was not anything about opioids.

1 I just said: Does Medicaid status, as far as  
2 you know, also affect the measures that you are  
3 talking about that you are tracking --

4 MS. KEARSE: Object to form.

5 Q. -- including how often they're using OT,  
6 occupation or physical therapy services?

7 A. So I don't know how that direct -- the answer  
8 to Medicaid status and utilization. I just know in  
9 our comparator group, which was very high, we were  
10 able to compare to that group.

11 Q. Okay. So are you aware of recognized  
12 factors, other than the maternal drug use and Medicaid  
13 status, that affect the need for additional social  
14 services?

15 A. I'm not aware of that.

16 Q. Have you looked into that for any of your  
17 work on this case?

18 A. I have not.

19 Q. Are you aware of other factors that affect  
20 the incidence of educational deficits such as those  
21 that you are tracking?

22 A. We have stopped tracking the educational  
23 level of the mothers.

24 Q. I'm not talking about the mother.

25 A. Okay.

1           Q. I'm talking about the kids. For the  
2           offspring, one of the things you look at are some  
3           measures of essentially eventually once they get into  
4           school system and learning, how quickly they are able  
5           to what, speak, read? There are other measures of  
6           educational deficits that you track, right?

7           A. We are looking into that, correct.

8           Q. Are there other risk factors that affect  
9           those measures?

10          A. I'm sure there are.

11          Q. Do you know what they are?

12          A. I think it is multifactorial. I wouldn't be  
13          able to give you a direct answer.

14          Q. Did you look into any of those issues in  
15          connection with preparing your expert opinion in this  
16          case?

17          A. No.

18          Q. So in the research that you are doing, there  
19          is no effort to control for any potential confounders  
20          that would be related to the risk factors for  
21          educational deficits?

22                 MS. KEARSE: Object to form.

23          A. So we have applied for a grant with trying to  
24          add a control group, exactly, into our future study  
25          that we have applied for a grant. We have not



1 received it yet.

2 Q. So I think we have come around to where we  
3 started.

4 You've applied for a grant, but there is no  
5 ongoing research related to a way to have a  
6 accurate -- a representative control for all of the  
7 relevant -- as much as you can track -- risk factors  
8 for these sorts of deficits, needs for increased  
9 social services, et cetera, except for the fact of  
10 being born with NAS status; is that correct?

11 MS. KEARSE: Object to form.

12 A. So we could not find any great literature  
13 with a direct control group with the same  
14 socioeconomic status. I think when you do an  
15 administrative database review, it's -- it -- it is  
16 hard to separate those completely.

17 Q. So are you trying to do some sort of  
18 retrospective study or are you actually going to do  
19 prospective study with a control group?

20 A. We have a prospective.

21 Q. Do you know what the risk factors are or the  
22 criteria are that you are going to track to try to  
23 establish what is a good control?

24 A. So we are -- the main outcome -- the main  
25 first two steps are going to be opioid exposure and

1 non-opioid exposure and insurance status.

2 Q. What about all of the other stuff?

3 A. No.

4 Q. None of it?

5 You're not going to track any of the things  
6 that you have already identified that affect the need  
7 for social services, educational outcomes, Bayley  
8 scores, anything else?

9 MS. KEARSE: Objection.

10 A. We are going to be tracking all those. You  
11 asked how we are going to control.

12 Q. Okay. So to establish your control group,  
13 you need to have them be exactly the same as your  
14 exposed group, except for the fact of exposure, right?

15 That's the goal of controlled clinical  
16 research, right?

17 A. There is different -- you can control for  
18 certain factors and then you would then gather your  
19 data and then see if there is a significance when you  
20 break it down individually on certain other factors.

21 Q. So --

22 A. So our main two factors that we kept at the  
23 top as our breaking point were opioid and insurance  
24 status.

25 After that, we are going to look to see if

1     there is a difference in those two groups.

2           Q.   Do you know what other criteria you are going  
3     to look at, what other status you are going to look  
4     at?

5           A.   We are going to be looking at  
6     tobacco exposure. We are going to be looking at all  
7     of those previous outcomes of visual disturbances, OT,  
8     PT, everything else we are tracking in our clinic,  
9     except we are you now going to add a control group  
10    into our clinic.

11          Q.   So for tobacco use, you're talking about  
12    tobacco use while the mother was pregnant?

13          A.   Correct.

14          Q.   Okay. And there is literature that  
15    tobacco use while pregnant affects various measures  
16    like birth weight at the time of delivery, correct?

17          A.   Correct.

18          Q.   And those also have an association in the  
19    literature to a need for additional services and  
20    increased frequency of educational deficits,  
21    correct?

22               MS. KEARSE: Object to form.

23          A.   Only for certain aspects.

24          Q.   And one of those cites that you have in your  
25    report is to a study that looked at the incidence of

1 tobacco use in pregnant women by testing versus  
2 self-reporting.

3 Do you remember that?

4 A. Uh-huh.

5 Q. Yes?

6 A. Yes.

7 Q. That's another rule I didn't go over. It is  
8 helpful --

9 A. I forgot, yes.

10 Q. -- to answer with words and not nods or  
11 sounds.

12 So is one of the things that you would pay  
13 attention to with tobacco use is whether increased  
14 tobacco use while pregnant might be a confounding  
15 factor for the need for social services, for  
16 educational deficits or other things that look like  
17 long-term impacts of neonatal abstinence syndrome?

18 MS. KEARSE: Object to form.

19 A. I'm not aware of any of that literature.

20 Q. Is that part of what you are trying to  
21 examine in the paper that you are going to do if you  
22 get the funding?

23 A. We are -- it's -- that would be a part of the  
24 descriptive behavior.

25 Q. Okay. And is it true, as far as you know,

1     that there is a correlation between women who smoke in  
2     the third trimester of pregnancy and women who also  
3     use illicit drugs while pregnant?

4             MS. KEARSE: Object to form.

5             A. Not aware of that.

6             Q. Did you see that in the paper that you cited  
7     on tobacco use?

8             A. The way you asked is does cigarette use lead  
9     to opioid.

10            Q. I said is there a correlation between  
11    tobacco use during the third trimester of pregnancy  
12    and illicit drug use during pregnancy?

13            MS. KEARSE: Object to form.

14            A. The way you're asking if -- you would ask to  
15    ask it the other way.

16            Q. Okay. So you think that drug use during  
17    pregnancy, use of illicit drugs is associated with  
18    increased use of tobacco during pregnancy, not the  
19    other way around?

20            A. Correct.

21            Q. Are you going to track alcohol use during  
22    pregnancy in the study that you are proposing?

23            A. We look at self-report of alcohol use.

24            Q. So like what we saw in the tobacco paper,  
25    self-reporting tends to be about four to six times

1 lower than testing for the metabolism -- the  
2 metabolites of tobacco, correct?

3 A. That is correct.

4 Q. So self-reporting of alcohol is going to  
5 underestimate alcohol use during pregnancy, right?

6 MS. KEARSE: Object to form.

7 A. That is correct.

8 Q. And is there some correlation between alcohol  
9 use, illicit drug use, and tobacco use, those all go  
10 hand-in-hand?

11 MS. KEARSE: Object to form.

12 A. Alcohol hasn't really been looked at that  
13 much because there is no test to determine that use at  
14 a readily available process, and that's why we had to  
15 rely on self-report. It is purely a -- what lab test  
16 can you get?

17 Q. Okay. So why do you look at alcohol abuse  
18 during pregnancy?

19 A. We know that that can lead to fetal alcohol  
20 syndrome.

21 Q. Have you ever come up with a plan for how to  
22 improve outcomes with fetal alcohol syndrome in Ohio  
23 or any portion of Ohio?

24 A. I have not been part of that.

25 Q. Did you still have fetal alcohol syndrome

1 infants in your care or in the care at your  
2 hospitals?

3 A. We do.

4 Q. Have there been, as far as you know, public  
5 health efforts around the nation, and in southwest  
6 Ohio in particular, for as long as you've been a  
7 practicing doctor to try to reduce fetal alcohol  
8 syndrome?

9 A. It is part of the OB visits that are  
10 discussing decrease in use.

11 Q. And what about on your side, on the pediatric  
12 side: Do you participate in any of that at all in  
13 terms of counseling to try to avoid fetal alcohol  
14 syndrome and minimize its incidence?

15 A. We usually are on the other -- I mean, we  
16 work with the mother-infant dyad. So when we have a  
17 mom who is pregnant that we are seeing in the clinic,  
18 we obviously would -- if the questions come up, we  
19 would address it.

20 Q. And despite the efforts, you haven't been  
21 able to eliminate fetal alcohol syndrome?

22 A. That is correct.

23 Q. And anywhere in your report, do you talk  
24 about the impact of fetal alcohol syndrome on the need  
25 for additional public services or changes in hospital

1 behavior -- or healthcare behavior more generally with  
2 regard to pregnant women?

3 A. I do not mention fetal alcohol syndrome.

4 Q. I mean, is it possible to really talk about  
5 optimizing maternal and fetal care without talking  
6 about alcohol abuse, abuse of other drugs, tobacco,  
7 while you're talking about opioids and opiates?

8 MS. KEARSE: Object to form.

9 A. Can you repeat that one more time?

10 Q. Sure. I'll actually do better. I'll try to  
11 break it down.

12 So I just asked generally about alcohol  
13 abuse.

14 Alcohol abuse during pregnancy is a public  
15 health issue, correct?

16 A. Yes.

17 Q. Okay. And it has increased -- it is  
18 associated with increased healthcare expenditures,  
19 increased social services needs, educational deficits  
20 and a variety of other sequelae, correct?

21 MS. KEARSE: Object to form.

22 A. It is.

23 Q. Despite efforts for decades to try to  
24 eliminate it, right?

25 A. Correct.



1 Q. Okay. Other drugs, other than opioids or  
2 opiates, can be abused during pregnancy as well,  
3 correct?

4 A. That is correct.

5 Q. One of the things seen in your research, and  
6 the research you cited, is that while opiate abuse  
7 during pregnancy or opioid abuse during pregnancy has  
8 gone up during the same study period, basically all  
9 use of all drugs has gone up?

10 MS. KEARSE: Object to form.

11 A. Most, yes.

12 Q. In general, women now, according to the data  
13 that you have released to the years you've presented,  
14 are more likely to use drugs while pregnant than they  
15 used to be, and that's pretty much true across all  
16 classes of drugs?

17 MS. KEARSE: Object to form.

18 A. Yes.

19 Q. And cocaine abuse during pregnancy can have  
20 an impact both on maternal health and fetal or --  
21 health or health of the offspring, correct?

22 A. It can have effect on maternal health and put  
23 the infant at risk for certain conditions.

24 Q. And infants at risk for certain conditions  
25 certainly need additional -- on average, need more

1 services in the postpartum period, correct?

2 A. Correct.

3 Q. And then there is the debate that we have  
4 talked about, about how long they might need  
5 additional services, correct?

6 A. That is correct.

7 Q. Is that still a debate in your community of  
8 pediatricians who focus on issues like the impact of  
9 maternal substance abuse?

10 A. We don't do any extra testing or -- for  
11 infants if they're exposed to solely cocaine.

12 Q. So they need additional services in the  
13 hospital, correct?

14 A. If they're born premature from an abruption,  
15 but otherwise, no, they do not.

16 Q. And so the experience with cocaine is that --  
17 I guess coming out of all of the research from the  
18 crack epidemic -- is that there doesn't seem to be a  
19 long-term need for additional educational or social  
20 services support in those babies; is that correct?

21 A. They do need elevated social service  
22 follow-up, but that's because it is an at-risk  
23 infant.

24 Q. And is that because they were born with  
25 withdrawal from cocaine, or is that because they're in

1 a household with a mother who might be still abusing  
2 cocaine or the other socioeconomic status overlays  
3 that we have talked about?

4 MS. KEARSE: Object to form.

5 A. I would say with your middle statement that  
6 it is due with a mother using illicit substance while  
7 pregnant.

8 Q. So for any illicit substance used by a mother  
9 there is going to be a need for additional follow-up  
10 and monitoring, correct?

11 A. Correct.

12 Q. So even though that's part of your program,  
13 that is not specific to opioid or opiate abusing  
14 mothers, correct?

15 MS. KEARSE: Object to form.

16 A. That is correct. We do a safety plan for  
17 those that are exposed to illicit substances during  
18 pregnancy.

19 Q. So, for other categories, there is -- if you  
20 -- some of the data that you actually showed is that  
21 while prescription opioid abuse in Ohio among pregnant  
22 women has dropped, it has been passed by cocaine and  
23 benzodiazepines recently, correct?

24 MS. KEARSE: Object to form.

25 A. I don't think it has been passed.

1 Q. So cocaine is higher now, benzodiazepine is  
2 the last thing that was going up, prescription opiates  
3 is going down, and now the last time they were at the  
4 exact same level; is that right?

5 MS. KEARSE: Object to form.

6 A. They are very close together, correct, there  
7 now.

8 Q. What, like within a tenth of a percent?

9 A. They're very close, correct.

10 Q. Well, benzo use is going up and prescription  
11 opioid use is dropping?

12 A. Yes.

13 Q. Okay. So for the data for the last several  
14 years, since roughly 2005, prescription opioid abuse  
15 in Ohio has dropped and that is also seen in terms of  
16 the usage patterns in pregnant women, correct?

17 A. For prescription opioids, yes.

18 Q. Okay. So are there health consequences to  
19 the mother, the unborn child or the infant with  
20 benzodiazepine abuse during pregnancy?

21 A. So you asked these questions there.

22 So the first one: Is there increased risk  
23 for mother? If she's getting prescribed  
24 benzodiazepines.

25 Q. I was asking about abuse.

1 A. Abuse?

2 Q. I can start them over and break them up.

3 So for abuse of benzodiazepines, are there  
4 health risks for a pregnant woman?

5 A. So if a person is using a prescribed -- any  
6 prescribed medication in an illicit manner, yes.

7 Q. Okay. What are those health risks, as far as  
8 you know?

9 A. Well, they're -- put themselves at -- if  
10 they're not following a physician's order, they're  
11 putting them at risk for overdose. They are not aware  
12 of the other interactions that it can have with other  
13 medications or substances.

14 Q. All right. Do you treat pregnant women at  
15 all as a clinician?

16 A. As a clinician, no.

17 Q. And what about any prescriptions or treatment  
18 of women at all, other than infants and small  
19 children?

20 A. I do not write prescriptions for pregnant  
21 women.

22 Q. Do you have a DA license?

23 A. Yes, I do.

24 Q. And on what occasions are you prescribing a  
25 controlled substance?

1           A. So in the hospital, you -- we write for  
2 morphine, benzodiazepines, buprenorphine, methadone,  
3 but within the hospital that is a different -- you  
4 don't need a D -- that covers -- it is not part of a  
5 DEA separate licensure.

6           Q. And are those for children or adults?

7           A. Those are for newborns.

8           Q. Is there occasion outside of the hospital  
9 setting where you ever prescribe any of those  
10 medicines?

11          A. No.

12          Q. Sir, let's go back to benzodiazepine abuse.

13          A. Okay.

14          Q. Are there risks in terms of the unborn child,  
15 whether they be low birth weight, early birth,  
16 rupture, any other consequences to the pregnancy  
17 itself?

18          A. Not that I'm aware of by pure abuse. I don't  
19 know if there is not any literature on that.

20          Q. Have you looked into that for purposes of the  
21 report here?

22          A. No.

23          Q. What about cocaine abuse or alcohol abuse?  
24 Did you look at any of these issues related to those  
25 in terms of health consequences to mothers, unborn

1 children or children?

2 A. No. My focus was on the opioid exposed.

3 Q. And what about just in general nonopioid drug  
4 abuse? Well, actually, stop. I'll go back. I missed  
5 one.

6 Benzodiazepine abuse: Does that have any  
7 long-term or short-term impacts in children who are  
8 born of a mother whose abusing benzodiazepines?

9 A. It does not affect their hospital stay in the  
10 hospital. And then long-term, like I don't know if  
11 there -- we don't -- there is no special follow-up  
12 that we do differently.

13 Q. What about any other drugs of abuse during  
14 pregnancy?

15 Are you aware of anything indicating that  
16 other drugs, not -- not opioids or opiates, not  
17 cocaine, not benzodiazepines, not alcohol, but other  
18 drugs. I guess it could be PCP. It could be  
19 marijuana. It could be a variety of other drugs.

20 Are you aware of any impact those have on  
21 pregnant women?

22 MS. KEARSE: Object to form.

23 A. Once -- it would go back to that previous  
24 state of any illicit use of any substance that is not  
25 being monitored puts the woman at risk for having

1 interactions, or not knowing what dosage they're  
2 taking. So there could always be an effect that  
3 way.

4 Q. Did you do any specific research or valuation  
5 of the literature on this issue for your expert  
6 opinions in this case?

7 A. No.

8 MS. KEARSE: Counsel, is this a good time for  
9 a break? I think we have been going over an hour.

10 MR. ALEXANDER: I would like to just come to  
11 a close on this line of questioning, which will only  
12 take a couple of more minutes, if people's bladders  
13 can handle that.

14 MS. KEARSE: If it's a couple more minutes.  
15 I'll try.

16 BY MR. ALEXANDER:

17 Q. Sure. In terms of the pregnancy itself, any  
18 other drugs of abuse affect how long a pregnancy  
19 lasts, its likelihood of resulting in rupture, early  
20 delivery, low birth weight, any of those measures?

21 MS. KEARSE: Object to form.

22 A. Drug use.

23 Q. Drug abuse other than the specific substances  
24 we have gone over, like opioids, opiates, alcohol,  
25 cocaine and benzodiazepines?



1           A. I just -- I wouldn't know how to -- what  
2 specific drug are you --

3           Q. Any of them. Is there any other drug of  
4 abuse that is known to be abused by women who you're  
5 aware of that either you study, treat or followed  
6 literature on that affects pregnancy outcomes?

7           A. No.

8           Q. What about affects infants who are born from  
9 a woman who has abusing any of those additional drugs  
10 or substances?

11          A. It doesn't change our length of stay in the  
12 hospital besides setting up a safety plan for the  
13 dyad.

14          Q. So if a woman is using, let's say, marijuana  
15 while pregnant, and that's seen in your data,  
16 correct?

17          A. We did look at THC.

18          Q. It's increasingly common and it is more  
19 common than use of any prescription opioid, correct?

20               MS. KEARSE: Object to form.

21          A. I don't know the numbers off the exact -- off  
22 the top. I would have to look that up.

23          Q. But you would defer to the charts in your  
24 report, right?

25          A. Yes.

1 Q. And the ones that you have attached?

2 A. Correct.

3 Q. I would say in general: For anything that  
4 you published with your name on it, you expect that  
5 the data is accurate?

6 A. Yes, it is.

7 Q. Do you stand by the statements in your  
8 publications?

9 A. I do.

10 Q. All of the things that you have cited in your  
11 report, you chose to cite those specific pieces of  
12 literature?

13 A. Correct.

14 Q. You stand by those as standing for whatever  
15 you cited them for, right?

16 A. Correct.

17 Q. And are you aware of any specific areas where  
18 you think that the published reports or articles that  
19 you have cited are wrong in any way or you have  
20 disagreements with what they're proposing?

21 A. No, I do not.

22 Q. Okay. And I could say this probably in  
23 general and then we can hit that promised break.

24 There are some of these recommendations of  
25 professional organizations and governmental or

1 quasi-governmental entities that you have cited or a  
2 attached to your report, correct?

3 There's ACOG statement and there is a World  
4 Health Organization statements, correct?

5 A. Yes. I wouldn't know what you mean by  
6 "quasi" statements descriptor.

7 Q. I said quasi-governmental.

8 A. Okay.

9 Q. Anyway so we can call this professional  
10 statements if you want, but they're also sometimes  
11 from governmental entities or international entities,  
12 correct?

13 A. Yes.

14 Q. You cited them and attached them to your  
15 report?

16 A. I did.

17 Q. Is there -- are there areas where what you  
18 recommend be done in Cuyahoga or Summit County going  
19 forward are different than what they recommend?

20 A. I -- I'm sure there must be one or two  
21 statements that is different in my report than if you  
22 read their full report would be different in all of  
23 those separate entities.

24 Q. The one that -- the one that would leap out  
25 is that you are a little more bullish on using

1 buprenorphine as the primary therapy for treating  
2 children when they're born with neonatal abstinence  
3 syndrome than using Morphine; is that correct, or  
4 methadone?

5 MS. KEARSE: Object to form.

6 A. I don't know about the adjective "bullish,"  
7 but we have one of the few centers that have done  
8 research on buprenorphine use in infants, yes.

9 Q. And that's your first line?

10 A. In some of our hospitals, not regionally.  
11 Our recommendation is still methadone.

12 Q. Are you aware of any data in any of the  
13 things that you've cited, including those sorts of  
14 governmental or professional statements that you think  
15 is wrong or outdated or misrepresents trends in opioid  
16 use or neonatal abstinence syndrome?

17 A. So some of those reports are old, meaning  
18 they more than three years old; so, yeah, I am sure  
19 there is outdated information in all of them.

20 Q. Is there any recommendation in any of those  
21 statements that you no longer abide by?

22 A. You mentioned multiple, CDC, WHO, ACOG, so  
23 I'm sure we are not following all of those statements  
24 that have been published in the last four years  
25 because there's been an evolving field.

1 Q. You also are an advocate and you recommend  
2 universal drug testing, not just universal screening,  
3 right?

4 MS. KEARSE: Object to form.

5 A. Yes.

6 Q. And that is one area where not everyone  
7 agrees with you, correct?

8 A. That is correct.

9 Q. Including that there are state laws that may  
10 get in the way of that because it leads to, like,  
11 criminal referrals and things like that when a woman  
12 tests positive and, therefore, you might get women not  
13 willing to participate in drug testing, right?

14 MS. KEARSE: Object to form.

15 A. That hasn't been shown.

16 Q. Okay.

17 MS. KEARSE: Counsel, I think I gave you  
18 leeway. You were finishing up your area and now we've  
19 kind of gotten into a whole nother area.

20 MR. ALEXANDER: Yeah. So one -- one more  
21 question, if I can. Just one.

22 MS. KEARSE: Just one. I'm just trying to be  
23 ever hour, I would, you know, assume let's try and  
24 take a break, if we can.

25 MR. ALEXANDER: Okay.

1 MS. KEARSE: I don't know what is funny about  
2 that.

3 MR. ALEXANDER: Well, we don't always --  
4 we've had a number of depositions where we have gone  
5 two or more hours between breaks, but it's fine.

6 I'm also laughing at the idea that I'm going  
7 to ask one question, but I will try. I'll try.

8 MS. KEARSE: Or we can just take a break.

9 MR. ALEXANDER: No, because now I have a  
10 question that I want to ask, so --

11 Q. Dr. Wexelblatt --

12 MS. KEARSE: I want to take a break.

13 Q. -- is there any portion of your  
14 recommendation that you have set forth in your report  
15 that is specific to something that should be done for  
16 Cuyahoga and Summit County as opposed to what you  
17 would recommend for any other one or two of the 98  
18 counties in Ohio?

19 MS. KEARSE: Object to form.

20 A. No.

21 MR. ALEXANDER: Now is a good time for a  
22 break.

23 MS. KEARSE: Thank you.

24 THE VIDEOGRAPHER: We're now going off  
25 record. The time is 10:50.

1 (There was a brief recess.)

2 THE VIDEOGRAPHER: We are now back on record.

3 The time is 11:10.

4 BY MR. ALEXANDER:

5 Q. All right. Dr. Wexelblatt, do you have any  
6 of your testimony thus far you need to change or amend  
7 in any way?

8 A. No.

9 Q. I have some follow-up on a little bit of the  
10 stuff we were talking about before the break.

11 For the tracking of cocaine use in pregnant  
12 women in any of the research efforts that you're  
13 engaged in, do you go off of blood tests? Do you go  
14 off of self-reporting? How do you track that?

15 A. Regionally what we do is base it on maternal  
16 urine drug testing at the time of delivery.

17 Q. And do you find that you get more from urine  
18 testing than you do from self-reporting?

19 A. Yes.

20 Q. Do you -- do you do anything to track the  
21 issue of polypharmacy, which of the women have use of  
22 not just one drug of abuse, but multiple drugs of  
23 abuse, during pregnancy?

24 A. We do track that.

25 Q. Are you aware of any literature that

1 polypharmacy, you know, multiple drugs of abuse, can  
2 have a cumulative or additive effect in terms of the  
3 effect on maternal health, pregnancy outcomes, or the  
4 health or needs of the offspring?

5 A. So to answer the last part of that, we do  
6 know that if a baby is opioid exposed and has  
7 polysubstance, that they do have more of a need for  
8 adjunct therapy than that, that does not.

9 Q. Okay. And what about other polypharmacy  
10 where a woman is abusing not opioids, but multiple  
11 other drugs?

12 Is there any literature on any of those  
13 outcomes?

14 A. I'm not aware of any literature that looks at  
15 that.

16 Q. What about literature on the other part of  
17 what you just answered, which is an effect on maternal  
18 health or pregnancy outcomes from polypharmacy that  
19 does involve opioids or opiates?

20 A. On maternal health --

21 Q. Yes.

22 A. -- was the question?

23 Q. No, you answered about --

24 A. You had three questions.

25 Q. Yeah.



1 A. And I went with the third part --

2 Q. It was --

3 A. -- on the infant.

4 Q. Right. You answered about the infant.

5 I also asked about --

6 A. Okay.

7 Q. -- maternal health and pregnancy outcomes.

8 A. So for maternal health, we know that moms  
9 that are in monosubstance therapy, or MAT, do better  
10 than those that have polysubstance use when it refers  
11 to opioids.

12 And then with pregnancy outcomes, I don't  
13 think there's any differentiation besides on -- I  
14 assume "outcomes," you mean by gestational age or  
15 birth weight?

16 Q. Those sorts of measures, yes.

17 A. I don't think there is.

18 Q. And I wasn't clear from your earlier answer  
19 when I was asking about benzodiazepines.

20 Is there literature that's looked at whether  
21 benzodiazepines affect the health of offspring or the  
22 need for additional services or medical care?

23 I know you said you don't track that in your  
24 clinic.

25 A. That is correct. We do not track that.

1 Q. Are you aware of any literature that's looked  
2 at that issue specifically as whether maternal  
3 benzodiazepine use can affect the health of the  
4 offspring and their need for additional medical or  
5 social services?

6 A. I'm not aware of anything that would  
7 differentiate illicit or prescribed benzodiazepine use  
8 and outcomes.

9 Q. And the -- you mentioned the use of databases  
10 to do certain kind of tracking and analysis in a  
11 retrospective fashion.

12 A. I did mention that.

13 Q. Are there current databases that you're using  
14 for any research efforts?

15 A. We use -- for most of our database that we  
16 are using is our internal database, which is based off  
17 our EHR and billing data.

18 Q. Does it have a name, your database?

19 A. I would have to -- I'm not aware of the --  
20 it's -- we use our Epic database for our last paper  
21 that we used.

22 When we have databases for our studies, they  
23 were all through REDCap. That was inputted data.

24 Q. So do you know what the historic tracking is  
25 in that database of, like, how they figure out alcohol

1 use, cocaine use, polypharmacy, or the other sorts of  
2 things that we have talked about in terms of maternal  
3 drugs of abuse, substances of abuse, or other effects  
4 on maternal health, pregnancy outcomes, or the health  
5 of offspring?

6 MS. KEARSE: Object to form.

7 A. To generally answer the -- the main databases  
8 usually are using an administrative database, which is  
9 based on the ICD-9 or 10 billing codes, based on the  
10 hospital records.

11 Q. So a lot of the stuff we've been talking  
12 about is not going to be tracked, correct?

13 A. We've talked about a lot.

14 Q. Well so in terms of maternal drugs of abuse  
15 and substance abuse, that's all not necessarily going  
16 to be tracked with the level of detail that we're  
17 talking about and have polypharmacy and the level of  
18 smoking and things like that.

19 That's not in billing codes?

20 A. No, that's incorrect, actually.

21 Q. Okay. Your ICD-9 codes tracks all of the  
22 different substances of abuse during pregnancy?

23 A. So, yeah, there was a recent paper in which I  
24 didn't cite, but since you bring it up, I know there  
25 is a paper out there by Patrick, who is a senior

1 author, that looked at administrative databases with  
2 predictive use and to look at if you had a certain  
3 diagnosis, was it correlated with the chart.

4 So they looked at the diagnosis of NAS and  
5 correlated it to opioid use, and they found that the  
6 ICD-9 was 92 percent correlative, and the ICD-10 was  
7 98 percent correlative with direct patient -- with  
8 direct chart review.

9 Q. So do the billing codes track the level of  
10 smoking, the level of cocaine use, the specifics of  
11 polypharmacy? Do they have that level of detail from  
12 the databases that you're using?

13 A. It's either -- it's a yes or no. So you  
14 either use or you did not use. It does not have  
15 specific numbers.

16 Q. Okay. So there's no quantification of the  
17 timing of the substance abuse during the pregnancy?  
18 Like whether it's first, second, or third trimester?

19 A. Not for every single drug. Usually tobacco  
20 is broken into that, but other substances it's usually  
21 not broken down that detailed.

22 Q. And so for polypharmacy, will it check yes or  
23 no for polypharmacy, or will it give some sort of  
24 pull-down for all the various substances that are  
25 involved in the polypharmacy?

1 MS. KEARSE: Object to form.

2 A. It will list all the exposures, and then if  
3 it's more than one, it's poly.

4 Q. I'm sorry to go back to this, but the ongoing  
5 paper you have related to hepatitis C, is your  
6 expectation that that is always through the use of  
7 drugs that involve needles?

8 A. No.

9 Q. How else might a mother get hepatitis C and  
10 pass it on to a child?

11 A. So your -- can you repeat the first question?  
12 I think the way you asked it was if it was always  
13 correlated with.

14 Q. So I'll ask it again.

15 A. Yes.

16 Q. I mean, you can have her read it back, I  
17 don't care, but I can -- so what sort of drug use can  
18 be associated with maternal transmission of  
19 hepatitis C to a child

20 A. What we have found is that it's associated  
21 with maternal opioid use.

22 Q. So is that meaning that the -- they're taking  
23 prescription pills pursuant to a prescription written  
24 for them?

25 A. So the level that we are able to look at, if

1 it's illicit, we can only break it down -- when we use  
2 the word "illicit," it means it wasn't prescribed. So  
3 I can't differentiate usually between heroin or  
4 illicit use of Percocet, for example.

5 Q. Okay. So based upon how you understand  
6 hepatitis C is transmitted in human populations, how  
7 do you believe the mothers are getting the  
8 hepatitis C?

9 A. It's usually bloodborne. It is bloodborne.

10 Q. So is that associated with use of drugs that  
11 involve needles?

12 A. Yes.

13 Q. So do you know if any of that's going to be  
14 pursuant to a legal prescription written for them?

15 A. Can you repeat that?

16 Q. Sure. I mean, maybe you've covered it.

17 Do you think it's always related to the  
18 illicit opioid or opiate use, correct?

19 MS. KEARSE: Object to form.

20 A. So our breakdown I would -- I don't have that  
21 data in front of me, so I can't -- I don't know -- I  
22 couldn't answer that a hundred percent when I say  
23 "illicit" if we ever -- we look at illicit versus  
24 prescribed.

25 Q. I mean, is anybody getting prescribed opioids

1 or opiates where they're injecting themselves and  
2 sharing needles such as that it could be bloodborne?

3 A. I think there's literature to suggest that  
4 illicit use of prescription opioids is associated with  
5 illicit use of injectables.

6 Q. Okay. So I'm not trying to be difficult, but  
7 I'm trying to get to the actual time when the  
8 transmission happens and what you're looking at.

9 A. Uh-huh.

10 Q. Is that to get the hepatitis C, somebody is  
11 using an illicit drug that involves a needle, and so  
12 you can have bloodborne transmission, correct?

13 MS. KEARSE: Object to form.

14 A. To get hepatitis C is bloodborne.

15 Q. Okay. And can that also be transmitted in  
16 some other fashion, through unprotected sex or  
17 anything like that, or is it always going to be  
18 bloodborne?

19 A. I think that the current understanding is  
20 that it's always bloodborne.

21 Q. Okay. So that's never going to be directly  
22 from the use of a prescription opioid, correct?

23 A. If you -- you're -- can you get hepatitis C  
24 from illicitly using a prescribed opioid?

25 Is that your question?

1 Q. No, I didn't ask illicitly.

2 A. Okay.

3 Q. I'm saying: Can you get hepatitis C from  
4 using a prescription opioid in a legal fashion, like  
5 pursuant to a prescription written for the person who  
6 actually takes it?

7 A. No.

8 Q. Okay. So what you're alluding to is that  
9 there is some suggestion that some patients who  
10 ultimately are using heroin, or other needle-borne  
11 narcotics, are -- may have started with some other  
12 drug or series of drugs before they get into heroin,  
13 let's say.

14 That's what you're talking about, right?

15 A. Uh-huh. Yes.

16 Q. Okay. So by the way, in terms of that area,  
17 the issue of, like, drug abuse patterns and the  
18 neuropharmacology that relates to addiction, the  
19 societal patterns of what's sometimes called the  
20 gateway effect, whether that exists, doesn't exist,  
21 how often it exists, those are all areas where you do  
22 not hold yourself out as an expert, correct?

23 MS. KEARSE: Object to form.

24 A. Correct, in that I'm not an expert in that.

25 Q. You're an expert in pediatrics, correct?



1 A. Yes.

2 Q. And you hold yourself out as an expert in --  
3 I guess it's described in the report here --  
4 maternal-fetal issues related to opiate exposure; is  
5 that correct?

6 A. It is.

7 Q. Are there any other areas where you hold  
8 yourself out as an expert?

9 A. No.

10 Q. So, I mean, not to make it too simplistic:  
11 But when you went to medical school and you picked the  
12 area where you wanted to focus, all of your  
13 specialized training has been in pediatrics,  
14 correct?

15 A. Yes.

16 Q. Okay. And so you don't hold yourself out as  
17 an expert in treating pain, in pharmacology or  
18 neuropharmacology of treating pain, any of the other  
19 areas that we might talk about as being related to the  
20 use of prescription or illicit opioids or opiates,  
21 correct?

22 MS. KEARSE: Object to form.

23 A. It's a generalized statement, yes.

24 Q. What about, like, obstetrics? Are you an  
25 expert in obstetrics?

1 A. No.

2 Q. Have you ever, outside of your early medical  
3 experience, participated -- well, let me ask it this  
4 way: So in some of these treatment of the  
5 mother-child dyads, there's other healthcare  
6 professionals who are focused on the mother,  
7 correct?

8 A. We have specialists in our OPQC team that are  
9 maternal-fetal medicine, addiction medicine  
10 specialists, obstetrics, social workers, yes. We have  
11 every field covered.

12 Q. Okay. And even though you're talking about  
13 all of those fields here, your part where you're  
14 actually an expert is on the pediatrics side?

15 MS. KEARSE: Object to form.

16 A. I do take care of pediatric patients,  
17 correct.

18 Q. Do you hold yourself out as an expert in  
19 anything relating to the social services or  
20 educational support that might be required because of  
21 any kind of deficit in a newborn or a child?

22 A. So when we take care of the patient, it's the  
23 family that we are addressing. So if a -- the whole  
24 social service umbrella incorporates everything of the  
25 family.

1           Q.   So let me break it down because I can give  
2   some examples.

3                   You've already talked about occupational  
4   therapy and physical therapy and when those might be  
5   required and how those might correct some of the sorts  
6   of issues that you've identified, correct?

7           A.   That is correct.

8           Q.   So you're not an expert in occupational  
9   therapy or physical therapy, correct?

10                  MS. KEARSE:   Object to form.

11           A.   So to get into that field of OT or PT, they  
12   need a referral from us.   So we determine if they need  
13   those services.

14           Q.   Is that the extent of where you claim  
15   expertise?

16           A.   Yes.

17           Q.   Okay.   What about anything relating to social  
18   work or the sorts of social services that are  
19   typically provided on a county basis in Ohio?

20           A.   Once again, it's knowing that they have a  
21   need is our -- and then referral, and then  
22   letting them take over.

23           Q.   What about, like, the specifics of the social  
24   work or the social services part of that, how you  
25   would form a specific plan and what kind of staffing

1     you would need to implement additional care for a  
2     mother-child dyad affected by drug abuse?

3             Those specifics would be beyond your  
4     expertise as well, correct?

5             MS. KEARSE: Object to form.

6             A. That is correct.

7             Q. And, therefore, that's -- and that's part of  
8     why in your report you didn't outline any specifics of  
9     what you think -- actually think social services would  
10    need to provide, correct?

11            A. Exactly.

12            Q. And the same thing goes for any of these  
13    areas in terms of obstetrical care or any of the  
14    general topics that you've identified, that there  
15    would be need for some sort of plan or some sort of  
16    services to be provided to improve or -- I'm sorry --  
17    as you say, optimize maternal-fetal outcomes.

18            Those sorts of specifics would need to be  
19    provided by experts in the specific fields, not you?

20            MS. KEARSE: Object to form.

21            A. I agree with that.

22            Q. And there's nowhere where, for this case,  
23    you've gone forward and set out that level of detail  
24    about what a specific program would need to include at  
25    the level of detail that you would really need to

1 implement a program, correct?

2 MS. KEARSE: Object to form.

3 A. Depends on what you mean by "detail," yes.

4 Q. Well, I mean, we know that when it comes to,  
5 like, the actual treatment of NAS children in the  
6 hospital, when you initiate medication, how you might  
7 do nonpharmacologic therapy, the -- what you might do  
8 to provide different types of nutrition through breast  
9 milk or formula, those sorts of things.

10 There are extensive plans that have been  
11 published by you and by some of the entities that we  
12 talked about, right?

13 A. Yes.

14 Q. Okay. But in terms of the level of detail to  
15 say actually how you would implement a plan and what  
16 staffing you would need for a plan, what money you  
17 would need for a plan, on any of the other aspects of  
18 your report, that's not anywhere that you've adopted  
19 or referenced, correct?

20 MS. KEARSE: Object to form.

21 A. That's accurate.

22 Q. And as we said, the recommendations that you  
23 have across the board aren't specific to the needs of  
24 Cuyahoga or Summit County.

25 They're recommendations, I asked you before:

1 You would apply to any county in Ohio, but, in fact,  
2 pretty much anywhere where they have babies being born  
3 of mothers who are abusing drugs, correct?

4 MS. KEARSE: Object to the form.

5 A. This is purely on opioids abuse, yes.

6 Q. Other than that, my statement is correct?

7 A. Yes.

8 Q. And some of the things that you're  
9 recommending here are, frankly, recommendations you  
10 would have with maternal abuse of any substance,  
11 right?

12 MS. KEARSE: Object to form.

13 Q. Follow up when they go home to monitor for  
14 additional needs? The involvement of the family?  
15 Consultation with social services to evaluate things  
16 like outplacement needs, follow-up needs?

17 All of those things are the same things you  
18 would recommend with any kind of maternal abuse of any  
19 substance?

20 MS. KEARSE: Object to form.

21 A. Not necessarily.

22 Q. Okay. We would have to go through those one  
23 by one to figure that out?

24 A. Well I think that the social work aspect,  
25 what you mentioned there, was definitely one for any,

1 but there are specific follow-up differences that  
2 are for opioid exposed that are different.

3 Q. Okay. We'll go through that later on. I'm  
4 just going to give you a -- kind of a heads-up.  
5 Because one of the things that I think is important in  
6 your field, and I want to know if this makes sense  
7 because of how you do the research, and you work in  
8 public health, is that you need to get a bunch of  
9 stakeholders to actually implement any kind of change  
10 to affect public health.

11 As you say in your presentations, "It takes a  
12 village."

13 You think that's right, don't you?

14 MS. KEARSE: Object to form.

15 A. I do.

16 Q. Okay. So in terms of the stakeholders that  
17 you would need to participate to implement your  
18 general plan, kind of the end of your report, your  
19 recommendations for improving outcomes, these aren't  
20 just things that the county and people who work for  
21 these counties would directly do.

22 This would involve third-party hospital  
23 chains and healthcare practitioners making changes.  
24 It would involve potentially changes to state, local,  
25 and federal law.

1           It would involve actions or changes in  
2   behavior by a number of different actors or  
3   stakeholders, correct?

4           MS. KEARSE: Object to form.

5           A. I'm not sure about laws needing to be  
6   changed, but I think the other part of that question  
7   was probably accurate.

8           Q. Well, I mean, you didn't in any of your work  
9   here do kind of a feasible analysis to see if any of  
10   what you're proposing would run afoul of any laws or  
11   would be in other ways not feasible to be implemented  
12   in a particular county, correct?

13          MS. KEARSE: Object to form.

14          A. So what we -- what is in that report is  
15   something that definitely is not against any laws, if  
16   that's what -- that we are aware of, that I'm aware  
17   of, if that was what you were asking me.

18          Q. Yeah, kind of. I asked if you did any kind  
19   of analysis about feasibility, either in terms of  
20   whether laws or the way laws are implemented would  
21   need to be changed, or any other aspect of  
22   feasibility, which would include access to additional  
23   staffing and whether the third-party stakeholders that  
24   you would need to participate would be willing to  
25   participate?



1 MS. KEARSE: Object to form.

2 A. No feasibility study was done.

3 Q. Okay. So, for instance, in terms of, like,  
4 the issue of laws, and I -- we'll get to it when we  
5 get to specifics, but I want to make sure you  
6 understand what I mean as I go forward with my  
7 questions, because I want to make sure you actually  
8 understand my questions.

9 A. Yeah.

10 Q. So, like, one of the issues with universal  
11 involuntary testing of drugs in connection with  
12 maternal care is that there are places where there may  
13 be some obligation to report illicit drug use or other  
14 legal violations related to illicit drug use to  
15 authorities, correct?

16 A. We never do involuntary testing.

17 Q. Okay. So the women who come to any of the  
18 facilities where you work or where you have some say  
19 in terms of how they do testing, if they show up and  
20 you say: We have to do a test of your blood and your  
21 urine to figure out if you're using drugs, they're  
22 allowed to say: I don't want you to test my drug, but  
23 give me care anyway?

24 A. They have to consent to be tested, correct.

25 Q. Okay. And what if they don't consent? Do

1     they get care, or do they have to go somewhere else?

2             A.   We give them care.   We test the infant.

3             Q.   Okay.   So no matter what, the infant is going  
4     to be tested.

5             They don't have to consent to that?

6             A.   Mother does not need to give us consent to  
7     test the infant.

8             Q.   Okay.   So one of the things that's described  
9     in some of your citations is that there are potential  
10    ethical issues relating to doing this sort of testing.  
11    If it creates a -- even at first consent, an  
12    obligation to report somebody on for potential  
13    criminal prosecution or other legal consequences,  
14    including to, like, social services, where you might  
15    have implications for custody and things like that,  
16    right?

17            A.   Correct.   So at the time of that study, we  
18    knew Tennessee was a voluntary -- that was a criminal  
19    act.

20            However, I think that was written in 2014, or  
21    published.   I think that law has changed since 2016 or  
22    '18.

23            Q.   Do you know if there are any legal  
24    impediments for doing the sort of testing that you  
25    would recommend be done in Cuyahoga and Summit

1 County?

2 A. So in Ohio, I know there is not.

3 Q. What about, like -- let me ask this: You  
4 said that you've looked at the issue of whether the  
5 possibility of legal ramifications, whether they be  
6 prosecutions or custody actions, deter consent being  
7 given to test maternal blood and urine, correct?

8 MS. KEARSE: Object to form.

9 A. We did a study to see if there was an  
10 increase in home births in our region after  
11 implementation of universal testing, and we did not  
12 find that.

13 Q. Okay. Well is that the only potential  
14 outcome of women who aren't willing to undergo the  
15 testing? I mean, they could give birth somewhere  
16 else? They could go to a different facility.

17 They -- there are other options, right?

18 MS. KEARSE: Object to form.

19 A. So we did this regionally, so our region  
20 encounters -- there's 18 hospitals in our region, so  
21 they would have to make a significant -- and we  
22 haven't seen a decrease in our regional births, so  
23 nobody is leaving the region as far as we are aware.

24 Q. Does your region cross the river, right  
25 there, to Kentucky?

1           A. It does cross to Kentucky. It covers Indiana  
2 also.

3           Q. So is it your expectation that the risk of  
4 essentially legal implications from positive drug  
5 tests is not going to deter any opioid or  
6 opiate-abusing pregnant women from getting the kind of  
7 care that you recommend?

8           A. We have not seen any changes in our region  
9 since implementation.

10          Q. That's good, right?

11          A. It is.

12          Q. And what are the -- what are the benefits, as  
13 far as you're concerned, of having universal maternal  
14 testing with consent?

15          A. So there's multiple. One is what we found in  
16 our region, is that early identification that allows  
17 us to know all opioid-exposed babies almost at the  
18 time of delivery, so we can initiate the  
19 nonpharmacologic treatment of that infant right away.

20                   And this has led us to see a decrease in  
21 our percentage of infants that are needing  
22 pharmacologic treatment.

23                   If you look at our regional compared to the  
24 rest of the state, we are 12 percent lower in the  
25 percentage of infants that need pharmacologic

1 treatment.

2 Q. And what do you attribute that to, that  
3 improvement?

4 A. It's one that we can initiate the  
5 nonpharmacologic treatment right away. We have  
6 also -- our readmission rate, we -- it has not been  
7 increased, so we haven't seen any babies. Even though  
8 we've seen an increased incidence of opioid use, we  
9 haven't seen an increase rate of readmissions for NAS  
10 because we're not discharging babies home and having  
11 them withdraw at home. They're withdrawing in the  
12 hospital.

13 Q. So both of those are positive in terms of --

14 A. Correct.

15 Q. -- the health consequence for all of the  
16 affected individuals, correct?

17 A. That is correct.

18 Q. And they also have cost savings because 12  
19 percent less pharmacotherapy results in cost savings  
20 and resource savings, correct?

21 A. That is correct. Another large benefit is  
22 that we identify moms that have never been known to  
23 have a substance use disorder, and we can then get  
24 them into the care that they need to get in the  
25 hospital time.

1 Q. And is there any data suggesting that that's  
2 happening more often?

3 A. So we are -- I don't have data to show  
4 there's an increased rate from hospital to care, but I  
5 know there's an increase in care in our region.

6 Q. So let's go back to where we were.

7 You said that there's 12 percent less than  
8 the rest of Ohio in terms of pharmacotherapy initiated  
9 with NAS, correct?

10 A. That is correct.

11 Q. You said there's also a lower readmission  
12 rate in your region than the rest of Ohio?

13 A. I did not state that.

14 Q. So --

15 A. We haven't seen an increase in our  
16 readmissions for NAS even though the incidence of  
17 exposure has increased.

18 Q. Okay. And do you also attribute that to your  
19 program?

20 A. I think that we are not discharging babies to  
21 have them withdraw at home, which would make them be  
22 readmitted. So, yes, I do attribute it to that.

23 Q. And that's in part because of having the  
24 universal testing?

25 A. Correct.

1 Q. Okay. So have you done any kind of analysis  
2 of any of the cost savings associated with having  
3 universal testing, either -- just in terms of  
4 healthcare dollars or resources?

5 A. So we know that if you don't need  
6 pharmacologic treatment in that 12 percent, that that  
7 will decrease an average of 12 days of length of stay.  
8 So it would be the 12 percent times 12 days, times how  
9 many infants we have decreased.

10 Q. Right. So 12 days is about \$40,000,  
11 according to your data.

12 \$3,300 a day on average, right?

13 A. Yes, that is right.

14 Q. And then -- so 12 percent of the total,  
15 that's a significant cost savings by reducing the  
16 pharmacotherapy incidents, correct?

17 A. Right. So our region is around 25,000  
18 deliveries a year.

19 Q. Okay. And so if there is an impact on  
20 readmission, it would also have healthcare savings for  
21 that?

22 A. Yes.

23 Q. Do they have universal testing in Cuyahoga  
24 and Summit County?

25 A. No.

1 Q. You think they should, right?

2 A. Yes.

3 Q. You think they should have initiated it  
4 several years ago?

5 MS. KEARSE: Object to form.

6 A. I don't think the data was out there when you  
7 mean several years ago. I don't think our publish --  
8 our paper was published until 2014, and it was novel.

9 It was one center, one site. We hadn't  
10 really spread it. So our published paper was just on  
11 a solo hospital here in our region.

12 We then did spread it to our regional  
13 information, and then I think we really just published  
14 that at the -- we have never published it, but we have  
15 identified it through our OPQC database, so we just  
16 are learning about it.

17 Q. Okay. So through the coordination through  
18 OPQC, the results that you've had and the improved  
19 outcomes in savings related to your program, including  
20 universal testing of, mothers has been described to  
21 the OPQC participants from Cuyahoga and Summit County  
22 over the years, right?

23 A. So this data is just evolving, and so we have  
24 a -- we've never looked at all opioid exposed until  
25 the end of our data collection, so '17 to -- you know,



1 2017 to '18, so we've just finalized that collection  
2 data, which is what we're -- you know, are just  
3 starting to address.

4 Q. In meetings of OPQC, going back to when you  
5 were talking about the NAS initiative in 2014, during  
6 that entire time, have you been suggesting that you  
7 think that universal testing is better than just  
8 universal screening?

9 MS. KEARSE: Objection to form.

10 A. So we have had a phone call. One of our  
11 discussions was identification of the opioid-exposed  
12 infant, and, yes, that was one of the talks on it.

13 Q. And so that's, what, five years ago?

14 A. No. Within the last two years.

15 Q. Okay. Do you have any idea why they're not  
16 doing universal testing now in Cuyahoga or Summit  
17 County?

18 A. It takes a regional approach, so we're lucky  
19 enough in our region to have a collaborative where all  
20 of the hospitals get together.

21 And so if you have competing hospitals in a  
22 region and one says: I'm not going to do universal  
23 testing, then the whole region is not going to -- it's  
24 not going to work, because then they're going to defer  
25 to hospital A and B if they're not doing universal

1 testing but they know X and Y are doing universal  
2 testing.

3 So you need a whole approach as a community,  
4 and so we are lucky enough in our region to have one  
5 group to lead this, which is Cincinnati Children's  
6 Hospital. And I think the other regions are -- I  
7 don't know if there's collaboratives set up to  
8 collaborate nicely.

9 Q. Right. So the region in which Cuyahoga  
10 County resides and the region in which Summit County  
11 resides, those are separate regions, correct?

12 A. They are.

13 Q. Okay. So I'll ask about them separately.

14 Do you know anything about any history of  
15 discussions among the various hospitals in the region  
16 in which Cuyahoga County resides to -- about this  
17 issue of adopting universal testing?

18 A. There have been discussions, but no  
19 adaptations.

20 Q. Is there some hospital chain or hospital  
21 that's opposed?

22 A. I don't know if I could answer that question  
23 without confidentiality that we have established in  
24 our OPQC and OCHA database.

25 Q. What confidentiality would that be?

1           A. Relieving -- showing one hospital. We've  
2   always gone about de-identifying our hospital data  
3   because we don't want to say that this hospital is  
4   presumably doing better than this hospital because  
5   there's multiple factors that are resolved.

6           Q. So I'm not asking about how they're doing or  
7   what any data is.

8           I'm asking about the discussions that you've  
9   heard about in Cuyahoga County about who might be  
10   opposed to universal testing?

11           MS. KEARSE: Objection.

12           A. I've never sat in the room with all of the  
13   hospitals there to discuss that in Cuyahoga County.

14           Q. Or Cuyahoga County?

15           A. Cuyahoga County, yes, that county.

16           Q. So what about in Summit County, or the region  
17   where they are? Do you know anything about the  
18   discussion there about universal testing?

19           A. I do not know about that discussion at that  
20   regional level.

21           Q. But you know from your colleague there that  
22   they haven't adopted it?

23           A. I do, yes.

24           Q. And can you think of any legitimate medical  
25   reason, given the data that you think now exists, why

1 universal testing shouldn't have already been adopted  
2 in those counties?

3 MS. KEARSE: Object to form.

4 A. It takes a lot of work. You have to work  
5 with your county level social workers to -- because  
6 the number of referrals do increase. So we did --  
7 prior to initiating regional approach, we met with  
8 each one.

9 We -- it takes a lot of collaboration and  
10 extra work with the OBs on the front line, and so it  
11 took awhile for us to get this set up. Probably from  
12 the time of our first publication to initiation, it  
13 was probably an 18-month ramp up.

14 Q. Are either of those counties in the middle of  
15 a ramp up right now?

16 A. Not that I'm aware.

17 Q. So do you know if you need different  
18 stakeholders to initiate this in Cuyahoga County or  
19 Summit County in the sort of ones you described, OBs  
20 and hospital chains and stuff?

21 A. We have worked with -- so when we were  
22 initiating in the Cincinnati counties, the Ohio  
23 Hospital Association has been a good collaborator.  
24 Hospital CEOs are always necessary to participate in  
25 this, too, because it does cost money and takes away

1     their bottom line.

2             Q.   It costs money, but it has long-term  
3     savings?

4             MS. KEARSE:   Object to form.

5             A.   Correct.

6             Q.   All right.   So, how does it work that  
7     universal testing actually leads to these benefits  
8     that you're talking about?   Is it that when there is  
9     universal testing, you don't have to wait until there  
10    are symptoms of withdrawal to initiate appropriate  
11    therapy?

12            MS. KEARSE:   Object to form.

13            A.   That's one of the benefits.

14            Q.   Okay.   So if there are two possibilities, one  
15    is you don't have universal testing, you go off of  
16    self-reporting, which is known to be an underreporting  
17    for things like opioid use or other maternal drug use,  
18    the same way it is with tobacco use, correct?

19            MS. KEARSE:   Object to form.

20            A.   That is correct.

21            Q.   And so there's going to be a percentage there  
22    where there actually is fetal exposure to drugs, but  
23    you guys don't know about it until the child is born  
24    and you do testing of the meconium and whatever else  
25    you test for drugs, correct?

1 MS. KEARSE: Object to form.

2 A. Or they have signs and symptoms of  
3 withdrawal.

4 Q. And so by the time they have signs or  
5 symptoms or they get the results back of the testing  
6 that you do, you have lost time to initiate  
7 pharmacotherapy or more likely the nonpharmacotherapy,  
8 the supportive sorts of things, like the extra  
9 swaddling and other supportive therapies that you  
10 recommend?

11 A. The nonpharmacologic therapy is delayed.  
12 Pharmacologic usually isn't delayed because that  
13 doesn't happen. Usually what we found, it was around  
14 44 hours, so most of the time they're having signs and  
15 symptoms or that testing is back on the infant by that  
16 time.

17 Q. And is there some additional costs associated  
18 with the nonpharmacotherapy?

19 A. There's no additional cost, but we do observe  
20 babies longer if we know they're opioid exposed.

21 Q. Does that mean they stay in the hospital  
22 longer?

23 A. Correct.

24 Q. But that's -- that has also benefits, you  
25 hope, because they'll -- you'll reduce readmission?

1 A. That is correct.

2 Q. Okay. So the data that's been published that  
3 you've cited and you've worked on, some of that does  
4 look at some of the nonpharmacologic therapeutic  
5 interventions and their success in reducing length of  
6 stay and the amount of total drug that they would be  
7 given if they do need pharmacotherapy, correct?

8 A. Can you --

9 Q. Sure. I'll make it more general.

10 So you're aware of literature both because  
11 you've worked on it, because you've cited it, that  
12 looks at essentially the positive impact of some of  
13 the strategies for nonpharmacologic intervention in  
14 NAS babies, correct?

15 A. That is correct.

16 Q. And so, in general, the non -- let's do it  
17 this way: The majority of NAS babies will not require  
18 pharmacotherapy, correct?

19 MS. KEARSE: Objection.

20 A. That is correct.

21 Q. And your goal is to reduce the percentage  
22 that have pharmacotherapy essentially as low as  
23 possible through effective nonpharmacologic  
24 interventions?

25 A. That is correct.

1 Q. Okay. And your goal also is to reduce their  
2 total length of stay, correct?

3 A. Correct.

4 Q. And your goal is to reduce the amount of drug  
5 that they would be given in terms of, you know,  
6 morphine equivalent units, or whatever, and how long  
7 they're given drug if they do have to be given  
8 pharmacotherapy, correct?

9 A. That is correct.

10 Q. Okay. And in general, that's part of what  
11 the OPQC initiative has been tracking, those sorts of  
12 measures, right?

13 A. Yes.

14 Q. And they've generally improved in the right  
15 direction that you want for all of them since you  
16 started tracking them in around 2014, correct?

17 A. That is correct.

18 Q. Actually track them month by month across the  
19 state, don't you?

20 A. We do.

21 Q. Okay. And do you find that the counties with  
22 the program that you recommend, as opposed to, like,  
23 what they're doing up in Cuyahoga and Summit, actually  
24 have better results?

25 A. Can you -- you're asking if our region is



1 doing better than the other two regions?

2 Q. Yep.

3 A. I've compared our region to the statewide  
4 data, not individual county levels.

5 Q. Okay. So you know you're doing better than  
6 the state?

7 A. Correct.

8 Q. On all of these metrics?

9 A. Yes.

10 Q. Okay. And that isn't just a coincidence.

11 That has to do with having a better plan that  
12 includes universal maternal testing, correct?

13 MS. KEARSE: Object to form.

14 A. There's lots of things that go into it.  
15 That's one of it. And we are also one of the few  
16 regions that is using buprenorphine, as you mentioned  
17 earlier.

18 Q. So are they using buprenorphine as a first  
19 line up in Cuyahoga and Summit County?

20 A. No.

21 Q. Do you think they should be?

22 A. There's no great formulation yet for  
23 buprenorphine for infants, and the data is really only  
24 out of our region and Philadelphia. So that hasn't  
25 been widely adapted even in our region. We are still

1 focusing on the individual level.

2 So to recommend it as a first-line therapy in  
3 a nonresearch environment, I don't -- that  
4 recommendation is not there yet.

5 Q. I understand you're talking about, like,  
6 national recommendations, what you consider to be  
7 standard of care.

8 But you, Dr. Wexelblatt, as somebody in this  
9 area, thinks that buprenorphine should be the  
10 first-line therapy for NAS children, right, or  
11 infants?

12 MS. KEARSE: Object.

13 A. Not in every hospital setting. It depends on  
14 what your pharmacology support is at each hospital,  
15 how you can compound it. So our first-line therapy at  
16 some of our hospitals where we can compound it is  
17 buprenorphine. At other level 2 hospitals, or more  
18 rural settings, we use -- our recommendation would be  
19 methadone.

20 Q. Okay. That kind of breakdown of what you  
21 recommend, depending on the level of hospital, is that  
22 what's going on up in Cuyahoga County now?

23 MS. KEARSE: Object to the form.

24 A. No.

25 Q. You think they should be doing it the way you

1 are?

2 A. I think we have published a lot of  
3 information that has shown promising results.

4 Q. And you've been publishing that now over the  
5 last four or five years, correct?

6 A. Ish, yes. Six. Yeah.

7 Q. You think in your mind, Dr. Wexelblatt,  
8 there's enough information out here that Cuyahoga  
9 County, the different levels of hospitals, should be  
10 doing it the way you recommend and are doing it down  
11 here in this region?

12 A. So our recommendation of methadone is part of  
13 the OPQC protocol, so I know that those babies that  
14 are being treated with methadone are following our  
15 methadone protocol, which is -- which I know they are  
16 following in Cuyahoga County.

17 Q. Okay. So you have a staggered recommendation  
18 that there are certain types of hospital based upon  
19 their level, their ability to, what, compound?

20 A. Buprenorphine.

21 Q. Is this -- is this a compounding issue?

22 A. Yes, and it's also a long term. There's not  
23 been really any long-term studies at this point on  
24 buprenorphine treatment with infants.

25 Q. Okay. So let's go back to -- you have a

1 recommendation that you're following in this region  
2 that gives different first-line therapy  
3 recommendations depending on essentially the level of  
4 hospital and their capabilities, correct?

5 A. A recommendation is to pick one opioid in  
6 your hospital and follow that, opioid regimen  
7 protocol.

8 Q. Okay. And that is not what's going on up in  
9 Cuyahoga County as far as you know?

10 A. No. I know they are following that same  
11 recommendation, pick one opioid and utilize that in  
12 your hospital.

13 Q. And are there any up in Cuyahoga County where  
14 they're using buprenorphine as the first-line therapy  
15 at equivalent hospitals to where buprenorphine is the  
16 first-line therapy down in this region?

17 A. Not that I am aware of.

18 Q. Okay. And you think they should be doing  
19 that, right?

20 A. Like I said, it's still in the research phase  
21 that we're developing information, and I can  
22 understand why hospitals haven't adopted it yet.

23 Q. But you think using buprenorphine has, in  
24 your mind, already sufficiently shown superior  
25 performance to using methadone in the same setting for

1     treating infants with NAS who require  
2     pharmacotherapy?

3                 MS. KEARSE:   Objection.   Form.

4                 A.   We have shown improvement within the  
5     hospital, yes, of utilizing it.   Our hospital --  
6     initial hospital stay has improved by using  
7     buprenorphine.

8                 Q.   Do you think that there has been adequate  
9     testing on the safety and efficacy of buprenorphine in  
10    this indication?

11                A.   There has not been a great long-term study of  
12    any infants with buprenorphine treatment and their  
13    long-term exposures.

14                Q.   So do you think it has been adequately tested  
15    in the safety and efficacy or not so far?

16                MS. KEARSE:   Object to form.

17                A.   Yes, knowing that it's the same type of  
18    formulation that we would see in the adult, just with  
19    a little bit of a different compound.   It's not -- it  
20    has to be liquefied instead of just a tablet, like it  
21    is in the adults.

22                Q.   Okay.   So let's go to -- we've been talking  
23    about Cuyahoga County.

24                Summit County, same thing:   Are they  
25    following the recommendation, as far as you know, to

1 pick one depending on the level of hospital?

2 A. Yes.

3 Q. Okay.

4 A. They are following that.

5 Q. Are any of the hospitals in Summit County  
6 having buprenorphine as the first-line therapy?

7 A. Not that I am aware of.

8 Q. Okay. Are there hospitals there that you  
9 think have the same criteria as the hospitals here for  
10 the same level to be able to use buprenorphine as a  
11 first-line therapy?

12 A. I would be making an assumption of their  
13 capability, but I know that each county does have a  
14 level 3 hospital in their county.

15 Q. Okay. So based upon your standards, you  
16 think there should be at least one hospital in Summit  
17 County using buprenorphine as first-line therapy, but  
18 there isn't?

19 MS. KEARSE: Object to the form. Misstates  
20 his testimony.

21 A. I'm -- they -- our recommendation is to  
22 initiate one opioid at the hospital, so which opioid  
23 they pick, there's multiple variations.

24 Q. I'm asking about Dr. Wexelblatt's view about  
25 buprenorphine. I'm not asking about the OPQC

1 recommendation.

2           Based upon what you think is the right, you  
3 as the expert in this field, think is the best way to  
4 go for the best outcomes for NAS infants, you think  
5 that at least one Summit County hospital should be  
6 using buprenorphine as first-line therapy, but  
7 currently there isn't any one right now?

8           MS. KEARSE: Object to form. Misstates his  
9 testimony and argumentative.

10          A. I think if they want to utilize it in a  
11 research setting and continue to do research like we  
12 are on it, that would be great.

13          Q. Okay. And is buprenorphine used in this  
14 setting you think the standard of care now?

15          A. No.

16          Q. What's the standard of care?

17          A. Methadone or morphine.

18          Q. The use of buprenorphine in this setting,  
19 treating NAS babies who require pharmacologic  
20 intervention, is that an on-label or off-label use of  
21 that drug?

22          A. Off label.

23          Q. Do you think it's appropriate?

24          A. Yes.

25          Q. Is that a decision you came to on your own,

1 or is that the result of some sort of marketing  
2 information you got from the manufacturer of  
3 buprenorphine?

4 A. No, that is purely work -- research with  
5 collaborators.

6 Q. And so do you -- when you recommend the  
7 initiation of buprenorphine in this context, do you do  
8 some sort of additional disclosure that this is an  
9 off-label use?

10 A. Almost every drug we use in the NICU is off  
11 label.

12 Q. So that's a no? You don't give them extra  
13 information, frankly?

14 A. That is correct, unless they are  
15 participating in a research study, which we have done.

16 Q. For research studies, do you have a consent  
17 form, and somewhere in there it says: By the way,  
18 this is exploring a new indication that's not part of  
19 what's approved for this drug?

20 A. Correct.

21 Q. So the same thing goes for use of methadone.  
22 Is methadone in infants off label?

23 A. Yes.

24 Q. You think it's appropriate?

25 A. Yes.



1 Q. And use of -- what was the third one?

2 A. Morphine.

3 Q. Morphine.

4 Morphine is also off label to be used in  
5 infants to treat NAS, correct?

6 A. That is correct.

7 Q. Same thing goes for those: You don't have  
8 any kind of additional consent for normal clinical use  
9 outside of a clinical trial, correct?

10 A. That is correct.

11 Q. Okay. In this area, you don't see anything  
12 wrong at all with using these drugs in this off-label  
13 fashion, correct?

14 A. Correct.

15 MS. KEARSE: Object to form.

16 Q. And, in fact, it's standard of care, right?

17 A. Yes.

18 Q. And part of what you're recommending  
19 globally -- I know you're not necessarily telling  
20 everybody which drug to pick in which hospital -- is  
21 to address the impacts of the opioid or opiate  
22 epidemic in parts of Ohio through the off-label use of  
23 prescription pharmaceuticals; is that correct?

24 MS. KEARSE: Object to form.

25 A. We are recommending an off-label use of the

1     opioids, correct.

2           Q.   And would you need to do anything extra in  
3     terms of deal with, like, a county or a state to have  
4     them essentially endorse an off-label use based on  
5     your experience?

6           A.   Like I mentioned, every drug -- almost every  
7     drug we're using in the NICU is off label, so we --  
8     it's the standard of care to use off-label drugs in  
9     the NICUs.

10          Q.   Are you ever the one to prescribe a drug to  
11     the mother?

12          A.   No.

13          Q.   People on your team do that, right?

14          A.   People on the OPQC -- yes.

15          Q.   But on the team at your hospital, as part of  
16     the treatment of the mother-child dyad, somebody is  
17     the one prescribing medication to the mother,  
18     including the prescription of buprenorphine and other  
19     drugs, to get through the pregnancy or to aid in any  
20     sort of treatment of the opioid abuse, correct?

21               MS. KEARSE:  Object to form.

22          A.   That is correct.

23          Q.   And it -- as far as you know, that's also off  
24     label, using that in a pregnant woman?

25               MS. KEARSE:  Object to form.

1           A. I'm not sure if it's off label for pregnant  
2 women.

3           Q. But as far as you understand, there is a  
4 standard of care treatment of pregnant women that  
5 involves medical professionals prescribing scheduled  
6 opioids and opioid antagonists as therapy for pregnant  
7 women?

8           A. MAT is part of the standard of care for  
9 pregnant women.

10          Q. Okay. And is there any kind of carve-out  
11 that you're aware of where it's, here's what's  
12 appropriate for MAT, but once they're pregnant, you  
13 have to stop?

14          A. So I know that's -- when you talk about  
15 naltrexone and naloxone, we try to get them only on  
16 buprenorphine or methadone for the moms.

17          Q. Why is that?

18          A. Just the literature about the safeties of  
19 those and the long-term outcomes in the pregnancies.

20          Q. And you also try to avoid withdrawal of the  
21 mother during pregnancy, correct?

22          A. Yes.

23          Q. And that's one of the things that has been  
24 addressed in the literature, is that the maternal and  
25 fetal outcomes, including, like, early delivery, low

1 birth weight, etcetera, those are affected when  
2 there's an attempt to essentially get the mother to  
3 stop using -- or stop abusing opioids or opiates  
4 during pregnancy, correct?

5 A. We do not recommend detoxification during  
6 pregnancy.

7 Q. Is that different than what I said about  
8 getting -- trying to get somebody to stop using at  
9 all?

10 A. Yes. So we wouldn't want to wean somebody  
11 who's -- comes -- is on MAT, becomes pregnant. We  
12 wouldn't want them to take themselves off their  
13 prescribed methadone or buprenorphine.

14 Q. Are you ever the one to counsel a woman who  
15 is pregnant and using, or abusing an illicit drug,  
16 like heroin or one of these other medications that  
17 you've been studying, about what the options are  
18 relating to continuing or voluntarily discontinuing  
19 the pregnancy?

20 MS. KEARSE: Object to form.

21 Q. Has that ever come up?

22 A. We get involved when they're stabilized in  
23 their MAT, but we do meet with moms prior to delivery  
24 if they're -- once they're in a program in our  
25 region.

1           Q.   What about, like, early on in the pregnancy,  
2   in the first trimester?  Are you ever, Dr. Wexelblatt,  
3   involved in any kind of counseling about you're now  
4   pregnant, and you're abusing a drug, and here might be  
5   your options relating to the health of the child and  
6   decisions about the pregnancy?

7           A.   We are not involved in that.  I am not  
8   involved in that discussion.

9           Q.   Are you aware of what those discussions are  
10  like at your hospital?

11          A.   I know, from working with our OB colleagues,  
12  what those discussions are about non-detoxification  
13  and stabilization.

14          Q.   What about -- is there any discussion at all  
15  about whether patients who are within a certain window  
16  where it would be legal in Ohio to voluntarily  
17  terminate pregnancies where there's abuse of heroin or  
18  one of these other illicit drugs?

19               MS. KEARSE:  Object to form.

20          A.   Not aware of that ever occurring.

21          Q.   But you -- are you ever involved in the  
22  contraception discussion postdelivery to encourage  
23  somebody to go on, like, a long-acting reversible  
24  contraception?

25          A.   I don't personally have that conversation

1 with the mother, but I know the OBs do.

2 Q. And that's part of your recommendation, is  
3 that should be -- I mean, that's recognized literature  
4 that you've cited, is that's an important public  
5 health thing, is trying to reduce unintended  
6 pregnancies, correct?

7 MS. KEARSE: Object to form.

8 A. Yes, that is correct.

9 Q. And is that something you consider to be part  
10 of your overall proposal here, is that as much should  
11 be done as possible to reduce unintended pregnancies  
12 among drug abusing women in Cuyahoga and Summit  
13 County?

14 A. I wouldn't use the word "drug abusing." It's  
15 anybody in a -- substance use disorder would be a  
16 better word.

17 Q. Okay. So is it your view, or your opinion as  
18 part of your plan, that as much should be done as  
19 possible to reduce unintended pregnancies among  
20 somebody with a diagnosed substance abuse disorder in  
21 Cuyahoga and Summit County?

22 A. Yes.

23 Q. Okay. The data right now is that about 80  
24 percent of the pregnancies in this population are  
25 unintended, correct?

1 A. And what do you find as "this population"?

2 Q. Well, I mean, this --

3 A. Yes.

4 Q. -- I'm quoting you from your report, so...

5 A. Yes. If you're talking about opioid use,  
6 yes.

7 Q. You think it's different with other substance  
8 abuse?

9 A. I just didn't know what population, if you're  
10 talking Summit County, Cuyahoga County, Hamilton  
11 County, or just general.

12 Q. Is it different in those different counties,  
13 or do you only have national or statewide data?

14 A. I didn't know if you were just talking 80  
15 percent of all pregnancies.

16 Q. I'm asking separate. Okay.

17 So in this country, a high percentage of all  
18 pregnancies are considered unintended, correct?

19 A. Correct.

20 Q. And from a public health perspective,  
21 reducing unintended pregnancy is generally considered  
22 a good thing, right?

23 MS. KEARSE: Object to form.

24 A. Yes.

25 Q. For all populations, not just opioid abusing

1 or people with a substance abuse disorder, correct?

2 A. We know that it's associated with  
3 prematurity, so, yes.

4 Q. Among other things?

5 A. Correct.

6 Q. There are -- there are a number of negative  
7 consequences on a population basis of unintended  
8 pregnancy, and doctors and people who care about  
9 public health want to reduce the percentage of  
10 unintended pregnancies in all populations, not just  
11 those who abuse drugs, correct?

12 A. Correct.

13 Q. Okay. And when you talk about it would be  
14 advisable to reduce the percentage of unintended  
15 pregnancies from 80 percent in women who abuse opioids  
16 or opiates, you also think it would be good to reduce  
17 the rate of unintended pregnancy in women who are  
18 abusing any substance or combination of substances,  
19 right?

20 MS. KEARSE: Object to form.

21 A. I would change the word "abuse" to anybody  
22 with a substance use disorder, once again.

23 Q. Otherwise agree with that?

24 A. That decrease in the rate of short-term  
25 interval is a good thing, if that --



1 Q. So why are you saying a short-term interval?

2 A. That's a medical -- you're saying the same  
3 thing that I am.

4 Q. Okay.

5 A. Short term between pregnancies, so, yes.

6 Q. Got it. That's a whole other thing.

7 A. Yeah.

8 Q. You actually don't want a woman who has a  
9 substance abuse disorder who's just delivered a child  
10 to have an unintended pregnancy close in time because  
11 that has additional negative impacts on the  
12 development and health of the first child?

13 A. No, it's the pregnancy.

14 Q. The pregnancy?

15 A. Yes.

16 Q. Doesn't it also --

17 A. That's the prematurity.

18 Q. Doesn't it also affect the data on the  
19 behavioral, educational, and social services needs of  
20 the first child if there is an additional second  
21 pregnancy in the same drug abusing mother?

22 MS. KEARSE: Object to form.

23 A. So are you talking about illicit use only,  
24 then? Because you're saying "drug abusing."

25 Q. Yep.

1           A.   So I don't know how you would differentiate  
2   that.   I'm not aware of that data.

3           Q.   Makes sense, though, doesn't it?

4           MS. KEARSE:   Object to form.

5           A.   I don't know how -- the impact would have on  
6   the infant that was already born?

7           Q.   Right.   So, like, splitting attention, and if  
8   there are going to be two children under the age of 2  
9   in a household, that, statistically speaking, is close  
10   to 90 percent likely to be on Medicaid, that is likely  
11   to have exposure -- increased exposure to trauma and  
12   violence and abuse, to have increased incidence of  
13   housing uncertainty and food uncertainty.

14           All of those sorts of factors that you lumped  
15   under socioeconomic status, those are all known to  
16   have implications for behavioral, educational, and  
17   social services needs of children, right?

18           MS. KEARSE:   Object to the form.

19           A.   In that specific example you gave with all of  
20   those negatives, correct.

21           Q.   And any one of those negatives is also known  
22   to have negative implications for the social services,  
23   medical, and educational needs of children, right?

24           MS. KEARSE:   Object to form.

25           A.   Each one individually, yes, but I don't know

1 about the short term -- we don't see twins. When  
2 you're saying that it would deter the infant's  
3 attention, I don't think we've seen that.

4 Q. Okay. So is there any effort going on right  
5 now, when you talk about the control study that you're  
6 applying for a grant to do, where you would be able to  
7 get down to the level of tracking the real world  
8 individualized inputs or factors that would affect  
9 behavioral, educational, and social services needs of  
10 children other than just socioeconomic status?

11 MS. KEARSE: Object to form.

12 A. So our hope, if we're going back to this  
13 other -- a control group, if we can pick the biggest  
14 header that would control for most of those, then we  
15 would address it. So if we know that we can match  
16 insurance type of public versus private, then most of  
17 those -- all of those socioeconomic status stuff  
18 should be equal. We look at it and we track it to  
19 see if it is.

20 Q. Well what are you going to look --

21 A. You can't do it up front. That's not  
22 possible.

23 Q. What are you going to look at and track? Are  
24 you going to track, like, exposure to violence?  
25 Abuse? Housing uncertainty? Food uncertainty? You

1 know, number of moves a year?

2 Like what are all of the factors you would  
3 track?

4 A. So regionally we would assume, if you're in  
5 the same region with the same socioeconomic status,  
6 all of those should be equal.

7 Q. Except now you have the overlay of one is  
8 somebody whose mother is abusing drugs, and one is  
9 not.

10 A. Not always abusing drugs. Sometimes they're  
11 substance -- they're exposed, but they're not  
12 abusing.

13 Q. Okay. So in any of your data, are you going  
14 to break it up by the way it is for people who are  
15 abusing as opposed to having medically supervised  
16 legal use of prescription opioids?

17 A. We'll be tracking illicit versus  
18 prescribed.

19 Q. Okay. Currently is there information that  
20 shows that any of these outcomes are worse with  
21 illicit use of opioids versus medically supervised  
22 legal use of prescription opioids?

23 A. Which measures?

24 Q. Any of the measures you think are important  
25 to track the negative impacts of neonatal abstinence

1     syndrome, short term or long term?

2             A.   So we know there is a difference in illicit  
3     versus prescribed opioid use in NAS on some factors,  
4     yes.

5             Q.   Which factors, sir?

6             A.   So, we know percent that need pharmacologic  
7     treatment of stabilized MAT does -- the longer you're  
8     in it is better.

9             We know that babies that have illicit use  
10    show their onset of symptoms earlier than those with  
11    prescribed, and sometimes that means they have a  
12    shorter hospital stay.

13            And from a long-term out -- long term we  
14    don't have that data yet that we have -- nobody has  
15    really done that research yet.

16            Q.   Do you have an opinion, as you sit here  
17    today, as to whether the long-term data is going to be  
18    worse with illicit use of things like heroin and  
19    fentanyl analogues versus just a mother who at some  
20    term -- point during her pregnancy was taking a  
21    prescription opioid under the supervision of a  
22    doctor?

23            A.   I don't have that data at this time. I don't  
24    know that data.

25            Q.   Does any of the work you've done so far break

1 it up that way, where you can say: Here's what we're  
2 seeing with illicit abuse of substances like heroin  
3 versus somebody whose -- where the infant's exposure  
4 during pregnancy was just from prescription opioid  
5 being used under the direction and prescription of a  
6 licensed healthcare professional?

7 A. So we do look at some of our papers short  
8 term -- short acting versus long acting. So the long  
9 acting would only be methadone and buprenorphine. The  
10 short acting would lump heroin and Percocet  
11 altogether, and so there have been differences there.  
12 And --

13 Q. But back to my question: The answer is, no,  
14 we don't have any data yet that looks at impacts on  
15 NAS short term or long term and breaks them up based  
16 upon whether the in utero exposure was pursuant to  
17 illicit use of drugs or pursuant to all legal use of  
18 prescription opioids under the direction of a licensed  
19 healthcare professional?

20 MS. KEARSE: Object to form.

21 A. I think we did look at one of our papers that  
22 had illicit versus prescribed. I would have to go  
23 through them all to find that reference.

24 Q. Do you know which one that was? Maybe I can  
25 save you a step.

1           A. I think our very first paper, Hall  
2     Wexelblatt -- the OCHA study in 2014 in Pediatrics  
3     looked at that.

4           Q. Okay. That doesn't have long-term outcomes,  
5     does it?

6           A. It does not.

7           Q. And do you have an opinion, as you sit here  
8     today, that there are better or worse long-term  
9     outcomes based upon legal use versus illegal use by  
10    mothers who deliver NAS children?

11          A. We don't have that data at this time.

12          Q. And do you have an opinion, as you sit here  
13    today, as to the percentage of NAS babies in Cuyahoga  
14    or Summit County that are attributed to --  
15    attributable to illicit versus legal use of  
16    prescription opioids under the direction of a licensed  
17    healthcare professional?

18          A. I do not know their county-specific data.

19          Q. And none of the -- actually none of the work  
20    that you've done for this case so far, none of the  
21    opinions you intend to offer, breaks anything up by  
22    impacts of legal opioid use, where a doctor has  
23    prescribed an opioid to a patient who takes it legally  
24    under the direction of the doctor, versus all of the  
25    various types of illicit drug use, including heroin,

1 fentanyl analogues, combination of drugs on the  
2 street, all of that?

3 MS. KEARSE: Object to form.

4 A. Yeah. From the infant side, they don't care  
5 why they're exposed to the opioid. It's either  
6 they're exposed or not exposed.

7 Q. I understand that.

8 But I'm saying: For the opinions you intend  
9 to offer in the case, you're not, like, offering your  
10 opinion where you're going to say, I can break this up  
11 in terms of here are the impacts or here is the need  
12 to do something different solely related to the legal  
13 use of prescription opioids, correct?

14 MS. KEARSE: Object to form.

15 A. So we do recommend prescription MAT over  
16 illicit use, so that would not fall into your category  
17 there.

18 Q. So let me break it up, then.

19 So one of the things that you talk about in  
20 general, one of your identified topics, is the impact  
21 of the opioid or opiate epidemic in Ohio, including  
22 Cuyahoga and Summit County, correct?

23 A. That is correct.

24 Q. When you provide those opinions, none of  
25 that -- none of those opinions are broken up to say,



1 here is how much of this I think is related to illicit  
2 use versus legal use, correct?

3 A. I did not break that up, correct.

4 Q. And for your proposals, although clearly  
5 you're suggesting that legal use under the guidance of  
6 licensed healthcare professionals as part of MAT or  
7 pharmacotherapy of NAS infants, you're also not  
8 breaking up anything about your outcome -- the  
9 proposals you have to address these impacts based upon  
10 legal use versus illicit use?

11 MS. KEARSE: Object to form.

12 A. I didn't break that out.

13 Q. Okay. You understand the issue, right? You  
14 understand the issue I'm highlighting for you?

15 A. Not entirely know where you're going, but...

16 Q. Okay. Well let me make sure I understand  
17 what you're opining on and what you're not opining on.

18 So nowhere in your intended testimony at  
19 trial will you offer some sort of cost of remediating  
20 or fixing any aspect of the opioid epidemic, including  
21 in NAS babies or any maternal issues?

22 You're not giving any cost opinions at trial,  
23 right?

24 MS. KEARSE: Object to form.

25 A. Just a generalized if you decrease the length

1 of stay, you're going to decrease the cost.

2 Q. Okay. So basically you have things you want  
3 to do to save money, save healthcare dollars?

4 A. All we're proposing -- yes, that's one of the  
5 goals, is to improve the outcomes.

6 Q. Okay. But you're not going to offer any  
7 opinions about how much any of your plan would cost if  
8 it were implemented in Cuyahoga County, Summit County,  
9 or both, correct?

10 A. That is correct.

11 Q. Okay. And you're certainly not offering some  
12 sort of opinion about how much it would cost to just  
13 address the portion of this that relates to people  
14 taking legal prescription -- legal prescriptions of  
15 prescription opioids?

16 MS. KEARSE: Object to form.

17 A. Correct.

18 Q. Okay. Do you have an understanding as to how  
19 much of the NAS you see is related to legal use versus  
20 illicit use?

21 A. I would have to go back to our data to look  
22 at that. I don't know off the top of my head.

23 Q. Okay. Do you have a -- like a majority is  
24 illicit? Do you have an understanding at that level?

25 A. I think a third is illicit.

1 Q. A third is illicit?

2 A. I think that's what we published in our first  
3 paper.

4 Q. Okay. So you think two-thirds, then, are  
5 people who are only taking while pregnant under the  
6 direction of a -- of a doctor and they're not using  
7 polypharmacy or some other illegal drugs at the same  
8 time?

9 A. So illicit opioid. So the nonillicit would  
10 include MAT and prescribed opioids.

11 Q. Okay. So --

12 A. So any prescribed opioid.

13 Q. What about the --

14 A. I just --

15 Q. I'm sorry. I didn't mean to cut you off.

16 A. I think that's what we published in our very  
17 first paper, was our illicit use back then.

18 Q. Do you have any opinions that would look at  
19 impacts or what to do to fix any of the impacts that's  
20 focused at all just on the prescription part of it?  
21 Like patients who got a legal prescription for an  
22 opioid and then took it pursuant to directions with no  
23 other illegal drugs at the same time?

24 MS. KEARSE: Object to form.

25 A. What would be my recommendation? Is that

1     what you're asking?

2             Q.   Do you intend to offer any opinions that's  
3     limited to just those issues?

4             A.   Yeah.

5             Q.   You do?

6             A.   That if you never get a prescription, you're  
7     never going to have NAS.

8             Q.   Okay.   So what about the percentage of people  
9     in Ohio who use heroin and heroin was the first drug  
10    they ever used?

11            MS. KEARSE:   Object to form.

12            Q.   That happens, right?

13            A.   I'm sure it has.

14            Q.   I mean, NAS has been described in the medical  
15    literature since, what, the 1970s?

16            A.   1975 was the first paper, correct.

17            Q.   I think I have it and have read it.   It was a  
18    page-turner.

19            But the NAS that's described in the earliest  
20    stuff was, what, related to methadone use in pregnant  
21    women, or is it related to heroin?

22            A.   Heroin.

23            Q.   So there have been withdrawal and specific  
24    clinical entity described from heroin use in pregnant  
25    women for more than four decades now, correct?

1 MS. KEARSE: Object to form.

2 A. That is correct.

3 Q. And do you know what percentage of the NAS  
4 babies that the drug use they have has only ever been  
5 legal?

6 Let me withdraw that. Let me -- let me fix  
7 it, I think, because we're including MAT, right?

8 Nobody's -- the people aren't starting with  
9 MAT unless they already have an addiction or a  
10 diagnosed disorder, correct?

11 A. That is correct.

12 Q. So, there's some portion of pregnant women  
13 who are getting a legal prescription for an opioid for  
14 chronic pain, for instance, right?

15 A. That is correct.

16 Q. And you have that in your hospitals,  
17 correct?

18 A. Yes.

19 Q. Sometimes prescribed by your colleagues,  
20 correct?

21 A. Yes.

22 Q. And you're not here to opine that  
23 prescription use of opioids in pregnant women for an  
24 indication like chronic pain is always wrong, are  
25 you?

1 MS. KEARSE: Object to form.

2 A. No.

3 Q. In fact, it may be completely appropriate and  
4 standard of care, correct?

5 MS. KEARSE: Object to form.

6 A. Yes.

7 Q. And when it comes to medical-assisted  
8 therapy, that is that somewhere along the line,  
9 somebody has an addiction disorder that may involve  
10 legal drugs or illegal drugs or some combination of  
11 them, right?

12 A. MAT is given in conjunction with behavioral  
13 therapy for people that have a substance use disorder.

14 Q. Do you intend to offer any opinions as to how  
15 often MAT is required where somebody has only ever  
16 taken a legal prescription in the amount given to  
17 them?

18 A. I do not know that information.

19 Q. I mean, so the way it would work is, like,  
20 you have a doctor, Dr. Wexelblatt, who writes a  
21 prescription for an opioid for a particular patient  
22 for an indication, and it has a certain drug and a  
23 quantity and a dosage, and they can take it pursuant  
24 to your recommendations, correct?

25 That's one way that somebody could be using

1 an opioid?

2 A. That is correct.

3 Q. Okay. Does that ever happen? Dr. Wexelblatt  
4 ever writes a prescription for an adult like that?

5 A. Do I --

6 Q. Yeah.

7 A. -- personally? No.

8 Q. Have you ever written an opioid prescription  
9 for an adult?

10 MS. KEARSE: Objection.

11 A. No.

12 Q. Have you ever written a prescription for an  
13 adult for anything?

14 A. Yes.

15 Q. Back in, what, residency? When would that  
16 have been?

17 A. Define adult age.

18 Q. Well 18 or up.

19 A. Yes, I have prescribed a -- an antibiotic for  
20 a person between 18 and 20.

21 Q. Okay. I'm not going to --

22 A. So that's -- pediatrics is allowed up to 21  
23 in some areas.

24 Q. Okay. Fine.

25 That's it, though? No --

1           A.   Correct.  No nonantibiotics outside of their  
2   indication.

3           Q.   Okay.  So do you know what percentage of the  
4   people who end up in MAT are only ever taking the  
5   prescriptions like you've described, which is, a  
6   doctor writes a specific prescription for a specific  
7   opioid in a specific dosage and frequency, and that's  
8   all the patient ever takes?  Never additional drug,  
9   never illegal drugs, never polypharmacy?

10           MS. KEARSE:  Object to form.

11           A.   I do not know those numbers.

12           Q.   And are you an expert on those sorts of data  
13   or those sorts of trends?

14           A.   No.

15           Q.   Do you intend to opine at trial as to how  
16   people get what their particular pathway is to get to  
17   where they might ever be on MAT?

18           A.   Restate that --

19           Q.   Sure.

20           A.   -- one more time, please.

21           Q.   So, like, in the data that you track on  
22   maternal drug use, you're tracking the use while  
23   pregnant, right?

24           A.   Correct.

25           Q.   You don't do some sort of deep dive to go



1 back to how they got their drugs, where they first got  
2 them, how much they were buying on the street, which  
3 particular, you know, dealers they use, whether they  
4 stole the drug, when they have ever, if ever, had a  
5 legal prescription taken legally?

6 Do you go to that level of detail ever?

7 MS. KEARSE: Objection.

8 A. Oh, we have that discussion often with the  
9 patient.

10 Q. And is that tracked in a systematic  
11 fashion?

12 A. Not tracked --

13 Q. Okay.

14 A. -- but...

15 Q. So do you -- do you have an impression as to  
16 how often it is that the patients -- you end up  
17 treating their children or their future children, how  
18 often it is that they're getting to require  
19 medical-assisted therapy where all they've ever done  
20 is taken a legal prescription of an opioid and never  
21 something else, something illegal, excessive,  
22 violating doctor's recommendations, any of that?

23 A. I have talked to many women that have had  
24 that pathway.

25 Q. And what about the later pathway, where along

1 the way they also use street drugs, they take  
2 additional drugs beyond what they're prescribed?

3 A. I've seen that pathway also.

4 Q. Okay. Do you intend to offer any opinions  
5 about how often either of those possibilities occur in  
6 your patient population?

7 A. I don't have a percentage of the patients I  
8 see, but I've seen those pathways.

9 Q. Both?

10 A. Correct.

11 Q. Do you hold yourself out as an expert in how  
12 to treat the mothers in this situation?

13 A. I -- the mother's addiction or the mother's  
14 best therapy for a pregnant woman to do with a  
15 substance use disorder?

16 Q. How to treat the mother's addiction.

17 A. So my -- I know the best course for her is to  
18 be in an MAT versus a nonsupervised setting.

19 Q. So for the work here, there is some data that  
20 you've cited that's specific to Summit and Cuyahoga  
21 County, correct?

22 A. That is correct.

23 Q. Typically from OPQC, that there is some data  
24 that's generated where you have it on a  
25 county-by-county basis, but there's some other

1 statewide kind of, I guess, databases that are  
2 utilized to get percentages of admissions involving a  
3 certain diagnosis, that sort of thing?

4 A. So the ODH and the OHA have databases that  
5 the information was collected from.

6 Q. And the ones that you've identified in  
7 connection with your report itself are the only  
8 Cuyahoga or Summit-specific data that you considered  
9 in forming your opinions, correct?

10 A. Those are the only ones I included in that  
11 report.

12 Q. Okay. Are there additional ones you  
13 considered in forming your opinions that you haven't  
14 disclosed?

15 A. I know -- I -- we have access to all of the  
16 counties, but did not put all 83 in the report.

17 Q. Do you --

18 A. The --

19 Q. -- intend to go get data on Cuyahoga and  
20 Summit County to supplement your report or look at  
21 additional data beyond what you've already  
22 disclosed?

23 A. No.

24 Q. So in this litigation, Cuyahoga County and  
25 Summit County are parties, and they've filed

1 complaints and they've produced documents in  
2 connection with the litigation, and they also have  
3 representatives and employees, current and past, who  
4 have given testimony.

5 Was that your understanding?

6 A. I'm not aware of what they've done.

7 Q. Have you ever looked at, like, complaints in  
8 this case that were filed by either Cuyahoga or Summit  
9 County?

10 A. No.

11 Q. Do you have an understanding of what they  
12 allege?

13 A. In a broad term maybe.

14 Q. Can you give me your broad understanding of  
15 what the counties allege?

16 A. That there was oversupply and overmarketing  
17 of opioids and overdistribution and over -- I guess --  
18 I don't know, the -- distribution.

19 Q. Based on your own personal knowledge as a  
20 doctor in Ohio who's dealt with doctors in those  
21 parts -- in those counties as well, do you intend to  
22 talk about whether any of the Plaintiffs' allegations  
23 are correct or incorrect relating to oversupply or  
24 marketing?

25 A. I haven't looked at their exact complaint,

1 but I do have -- know the statewide data, the number  
2 of prescriptions that we've seen statewide.

3 Q. And that's the extent of what you can do, is  
4 you can say, I know that the prescriptions have gone  
5 up over time?

6 A. Correct.

7 Q. And then they drop starting several years  
8 ago, right?

9 MS. KEARSE: Object to form.

10 A. They do decrease when we started working on  
11 this in 2012, correct.

12 Q. Right. So for the last seven years, the  
13 opioid prescriptions in Ohio have been dropping every  
14 year?

15 MS. KEARSE: Object to form.

16 A. I think so, yes.

17 Q. So do you know the names of any of the  
18 Defendants in this litigation?

19 A. No. Well, I take that back. I do know  
20 possibly two, I think.

21 Q. Who are the two you think you know?

22 A. Purdue and Cardinal Health.

23 Q. Okay.

24 A. I don't know if I'm correct.

25 Q. Do you intend to offer any testimony specific

1 to either of them, what they did or didn't do, or  
2 should or shouldn't have done?

3 A. No.

4 Q. And so the other, like, 15 defendants, you  
5 certainly aren't offering any opinions specific to  
6 their conduct, correct?

7 A. I didn't know there was 17.

8 Q. So let's go back to the allegations of the  
9 Plaintiffs and what their information is.

10 We talked about conversations you may have  
11 had through OPQC with people who work in those  
12 counties, correct? Remember that?

13 A. Uh-huh.

14 Q. And we talked about --

15 A. Yes.

16 Q. -- how you've seen some county-specific data  
17 along the way, correct?

18 MS. KEARSE: Object to form.

19 A. It's regional data for OPQC.

20 Q. I know --

21 A. You're talking about OPQC now.

22 Q. I'm not.

23 You've also seen some Cuyahoga and  
24 Summit-specific data from some of the sources that  
25 you've cited, correct?

1 A. That is also correct.

2 Q. So in connection with your role in this  
3 litigation, have you read any testimony given by  
4 anybody who is a representative of or ever worked for  
5 Cuyahoga or Summit County?

6 A. No.

7 Q. Have you looked at any of the documents  
8 they've produced in the litigation?

9 A. No.

10 Q. Have you looked at any of their discovery  
11 responses explaining what they think their harms were  
12 or what their particular allegations are, or any of  
13 those other things?

14 A. No.

15 Q. What about anything from the Defendants?  
16 Have you looked at any documents produced by any  
17 Defendant?

18 A. No.

19 Q. Do you have the ability to offer any opinions  
20 about whether any portion of any harm that's claimed  
21 by Cuyahoga or Summit County was caused by any action  
22 or inaction of any specific Defendant?

23 A. I would have no idea at this point without  
24 looking at anything.

25 Q. And the same thing goes for groups of

1 Defendants? You couldn't offer that testimony?

2 A. Wouldn't know who you were talking about, so,  
3 no.

4 Q. I didn't think so, but I'll spot you  
5 something: There are manufacturers, and there are  
6 distributors, and there are retail pharmacy  
7 defendants. Those are three ways that you might group  
8 this.

9 You're not going to talk at trial about  
10 anything the manufacturers as a whole did or didn't do  
11 and how that caused any harm, correct?

12 MS. KEARSE: Object to form.

13 A. Not my area of expertise.

14 Q. So you're not going to do it, right?

15 A. Yeah, I would assume not.

16 Q. Okay. I mean, that's kind of the way this  
17 works, is you disclose opinions, you claim expertise,  
18 and as I understand you, Dr. Wexelblatt, you're going  
19 to only try to offer opinions at trial that are  
20 disclosed within your area of expertise and where  
21 you've done enough research and evaluation that you  
22 can offer an opinion.

23 Am I right so far?

24 A. That is a hundred -- correct.

25 Q. Okay. So you're not going to offer any



1     opinions about what any group of distributors did or  
2     didn't do, or how that caused any harms, or what --  
3     anything would need to be done to try to fix any of  
4     that?

5             MS. KEARSE:   Object to form.

6             A.   That's correct.

7             Q.   Same thing for the other group of the  
8     Defendants, the retail pharmacies, correct?

9             A.   If they're mentioned, yes.

10            Q.   And so this brings us back to where we were  
11     about the issue of licit versus illicit drugs.   I am  
12     not sure you used the word "licit."   I just did.

13            But do you know what that means?

14            A.   Prescribed?

15            Q.   Well legal, yeah.

16            A.   Okay.

17            Q.   So -- because you could have a prescribed  
18     drug that's used illegally, right?   Like you could --

19            A.   Right.

20            Q.   -- steel somebody's prescription or you could  
21     give it to somebody else and then the use ultimately  
22     is illegal or illicit, correct?

23            A.   You could -- yes, that is correct.   You could  
24     illicitly use a prescribed substance.

25            Q.   In various ways, including buying and on the

1 street after it's been stolen from a pharmacy or a  
2 truck, or whatever, right?

3 A. That's one way.

4 Q. And in none of your opinions that you're  
5 intending to offer at trial are you going to focus on  
6 what you recommend or any description of the impact on  
7 NAS or maternal fetal outcomes based solely on the  
8 legal use of prescription drugs by the patient who's  
9 supposed to be taking them and taking them according  
10 to the directions of the doctor, correct?

11 MS. KEARSE: Object to form.

12 A. Yes, that is correct.

13 Q. You're also not going to be offering any kind  
14 of opinion, as I understand it, about how much things  
15 would be better if basically Cuyahoga and Summit  
16 County had been doing all of what you think had been  
17 reasonable from the time when you think they should  
18 have initiated it?

19 MS. KEARSE: Object to form. Misstates his  
20 testimony.

21 A. Yeah, I think it's unknown to say when --  
22 what would change it.

23 Q. Therefore, you're not doing that?

24 A. I don't know how to answer that question. I  
25 don't know what you're --

1 Q. Let me -- let me ask this complete question:  
2 Given that you don't know how things would be  
3 different if Cuyahoga and Summit County had taken  
4 additional steps over time to address NAS and maternal  
5 use of opioids and opiates while pregnant, you don't  
6 intend to offer any testimony at trial that basically  
7 focuses on what additional things would need to be  
8 done now if they had done what you thought would have  
9 been appropriate?

10 MS. KEARSE: Object to form.

11 A. It's a long question.

12 Q. It is. I've been told to try again.

13 Let me ask it this way --

14 MS. KEARSE: And I don't even know that it  
15 was a question.

16 MR. ALEXANDER: It was. It was -- it was  
17 most definitely a question.

18 Q. So, Dr. Wexelblatt, do you have an  
19 understanding at the level of detail of what's going  
20 on down in your region as to what Cuyahoga County is  
21 doing with regard to prevention, education and  
22 training, supportive services, and intervention now?

23 A. Their county compared to our county, do I  
24 know the differences?

25 Q. Yeah.

1           A.   No.

2           Q.   What about Summit County? Do you know at a  
3 level of detail what Summit County is doing now in  
4 terms of -- these are your areas of recommendation:  
5 Prevention, education and training, supportive  
6 services, and interventions, specific to neonatal  
7 abstinence syndrome and impacts on maternal use of  
8 opioids and opiates?

9           A.   I know that they are working on them all, but  
10 not to the level of detail that I could compare one  
11 county to another county.

12          Q.   So if we go back in time, do you know, like,  
13 what Cuyahoga County was doing on these -- in these  
14 broad areas back in 2010, '12, '14, '16, '18? Are you  
15 able to go backwards and say when they started,  
16 whatever additional efforts they started?

17          A.   I'm not able to do that right this second.

18          Q.   Do you intend to do that for trial, where you  
19 would basically do a comparison of what they've been  
20 doing versus what you think they should be doing going  
21 forward?

22          A.   I think -- don't know if there's anything  
23 that they should be that they aren't doing without  
24 going back in time and changing time.

25          Q.   Okay. So setting aside the time machine

1 option, you don't intend to offer the opinion at trial  
2 that Cuyahoga County should be doing something  
3 additional to what they're already currently doing in  
4 2019?

5 MS. KEARSE: Object to form. Misstates his  
6 testimony.

7 A. I would not know if every single thing that  
8 they have implemented at this time that would be in  
9 that report.

10 Q. I mean, your report doesn't really talk about  
11 what they're doing in Cuyahoga County and Summit  
12 County now, does it?

13 A. Our recommendations are pretty much universal  
14 that we know that there's a best -- sort of best  
15 practice that should -- implementation, and what they  
16 have done and not done, I am not aware of.

17 Q. Right. So just to make it clear, I was  
18 asking about Cuyahoga County.

19 For Summit County, you also don't know what  
20 they're doing now versus your recommendations,  
21 correct?

22 MS. KEARSE: Objection.

23 A. For all of them, you are correct.

24 Q. Okay. And for Summit County at points in the  
25 past, you don't know what they were doing then versus

1 your recommendations for what they should have been  
2 doing in the past?

3 A. For all of those recommendations, you are  
4 correct.

5 Q. So you don't intend to offer an opinion at  
6 trial as to anything that Cuyahoga County should be  
7 doing extra in 2019 compared to what they're doing  
8 already?

9 MS. KEARSE: Objection. That misstates his  
10 testimony.

11 A. Can you repeat that one more time? I --

12 Q. Sure. That was like the shortest one I've  
13 asked all day.

14 A. Yeah, I was just --

15 Q. I will.

16 You don't intend to offer an opinion at trial  
17 that Cuyahoga County should be doing anything extra in  
18 2019 compared to what they're already doing?

19 MS. KEARSE: Objection.

20 A. Not a hundred percent sure if they're doing  
21 all of that, but if they are not doing the  
22 recommendations, then I would recommend it.

23 Q. Okay. So sitting here today, are you in a  
24 position to offer any opinions that there are specific  
25 additional things that Cuyahoga or Summit County need

1 to be doing going forward compared to what they're  
2 already doing right now?

3 MS. KEARSE: Object to form.

4 A. It would be the recommendations in the report  
5 is what we would recommend them be doing.

6 Q. But you don't know how that relates to what  
7 they're already doing?

8 A. Countywide in each -- in the whole --  
9 throughout the whole county, correct.

10 Q. Or at any particular hospital in the county,  
11 can you provide the level of detail of saying at, you  
12 know, the Rainbow Health facility that's part of your  
13 consortium in Cuyahoga County, how their current  
14 practices relate to this and what they would need to  
15 change as much as this relates to hospitals as to  
16 other actors?

17 Can you do that?

18 A. Not at the -- every hospital-specific level  
19 in the county.

20 Q. Okay. And as we said, I mean, prevention,  
21 education and training, supportive services, and  
22 interventions, these are not just things you're asking  
23 that hospitals should do; these are things that you're  
24 asking various medical providers around the county  
25 should do, various public servants, you know, social

1 services, other employees of the county should do,  
2 what you want patients to do, what you would want to  
3 be in a public education campaign.

4 You're requiring a lot of actions not just by  
5 specific hospitals, but you're suggesting actions  
6 should be taken by a number of different actors in the  
7 communities, correct?

8 A. Correct.

9 Q. So going back to my question before: Sitting  
10 here today, you're not in a position to say any  
11 additional things that any actor in Cuyahoga or Summit  
12 County should be doing compared to what they're  
13 already doing now?

14 MS. KEARSE: Object to form.

15 A. If they're not doing it, then I would  
16 recommend them doing it.

17 Q. And sitting here today, you're not in a  
18 position to know what anybody is doing in these  
19 counties with regard to any of these  
20 recommendations?

21 A. I know in the general terms, certain parts  
22 are doing certain recommendations, but not every  
23 hospital in every county and every social worker in  
24 the whole county.

25 Q. And to do any of these things -- kind of the



1 Section 4 of your report -- there would need to be  
2 detailed plans put forward, and various people would  
3 need to sign on, correct?

4 MS. KEARSE: Objection.

5 A. It would be a regional approach, correct.

6 Q. And as far as you know, that hasn't happened,  
7 and you can't say if it ever would work?

8 MS. KEARSE: Object to form.

9 A. I can't say it has happened, and I think it  
10 would work if we implemented it.

11 Q. No. I mean, you can't say that all of the  
12 people who would need to participate would ever sign  
13 on and agree with your plan?

14 MS. KEARSE: Object to form.

15 A. I would hope they would.

16 Q. Okay. So do you know the difference between  
17 hope and being able to opine under oath that something  
18 is going to happen?

19 MS. KEARSE: Object to form.

20 A. Never used the word "opine" before, so I  
21 don't know.

22 Q. Let me see if I can ask this: Sitting here  
23 today, can you -- because it's in your report -- can  
24 you offer an opinion to a reasonable degree of medical  
25 certainty in the field of pediatrics and

1 maternal-fetal issues, as they relate to exposure and  
2 impact of in utero opioid exposure to infants, that  
3 the recommendations in your report would be adopted by  
4 all the necessary stakeholders in Cuyahoga or Summit  
5 County such that they actually would ever happen?

6 MS. KEARSE: Object to form.

7 A. Yes.

8 Q. Okay. So who would need to sign on to make  
9 all of those recommendations happen?

10 A. You would have to look at each one  
11 individually.

12 Q. Okay. And have you done anything to figure  
13 out if anybody up there agrees with you other than  
14 your particular OPQC contacts?

15 MS. KEARSE: Object to form.

16 A. It's been adopted from mostly -- the NAS has  
17 been adopted by our 52 hospitals that have  
18 participated, so I know that these are definitely  
19 reasonable approaches. And I know our -- part of our  
20 MOMS Plus project we have adopted in the -- our 29  
21 centers that are involved from that have adopted, a  
22 majority of these centers.

23 So, yes, this is definitely an approach that  
24 has been shown to work.

25 Q. Okay. I appreciate your answer, but it's not

1 actually the question I asked.

2 I'm asking about the stakeholders for  
3 Cuyahoga and Summit County who would need to sign on  
4 to make this work. It's not just hospitals.

5 It would need to be social services entities.  
6 It would need to be healthcare providers outside of  
7 hospitals. It would need to be families. It would  
8 need to be whoever does public education.

9 It would be a lot of different people as part  
10 of, you said, the village that it takes, right?

11 A. It would take a village, correct.

12 Q. Do you have the ability, as you sit here  
13 today, to say that basically Cuyahoga and Summit  
14 County would do all of these things?

15 All of the various actors that would be  
16 necessary to buy on, or sign on, would sign on the way  
17 they've done it down here in Cincinnati?

18 A. No reason to think they wouldn't.

19 Q. I'm sorry?

20 A. There's no reason to think they wouldn't.

21 Q. Would not; is that your --

22 A. Correct.

23 Q. Is that the best you can do?

24 MS. KEARSE: Object to form. Argumentative.

25 Q. Is that the best you can do in terms of

1 offering an opinion to a reasonable degree of medical  
2 certainty about these plans ever being adopted in  
3 these counties?

4 A. "Is that the best I could do" would mean?

5 Q. Well let me ask it directly: As you sit here  
6 today, can you opine that it is likely that every  
7 necessary stakeholder in Cuyahoga County would agree  
8 to make whatever additional changes were necessary to  
9 follow your recommendations?

10 A. I would think that it would be possible,  
11 yes.

12 Q. It would be possible?

13 A. Doable, yes.

14 Q. And so for Summit County, can you opine that  
15 it's likely that all of the necessary stakeholders  
16 would sign to take the additional steps to carry out  
17 your recommendations?

18 A. I do.

19 MR. ALEXANDER: I don't know how long we've  
20 been going, but now is probably a good time for a  
21 break.

22 MS. KEARSE: I was afraid to ask.

23 MR. ALEXANDER: And hopefully lunch is even  
24 here, so I would suggest a break unless somebody  
25 disagrees.

1 MS. KEARSE: Okay.

2 THE VIDEOGRAPHER: We're now going off  
3 record. The time is 12:44.

4 (There was a luncheon recess.)

5 THE VIDEOGRAPHER: We are now back on record,  
6 and the time is 1:26.

7 Q. Dr. Wexelblatt, is there any of your  
8 testimony from the period before the break that you  
9 need to change or supplement in any way?

10 A. Nope.

11 Q. I want to just follow up on, I think, where  
12 we were on a couple of things before the break.

13 The breakdown that you gave in some of your  
14 papers and that you can talk about here in terms of  
15 what drugs are being used in a mother who gives birth  
16 to a child who's ultimately diagnosed with neonatal  
17 abstinence syndrome, lumped together women taking MAT  
18 with those taking other legal prescriptions for  
19 opioids, correct?

20 A. We stated the differences in some papers,  
21 yes.

22 Q. So in none of your papers or the data that is  
23 being tracked is there a breakout of the legal  
24 prescriptions that are not including MAT versus MAT  
25 versus completely illicit -- illicit use of opioids or

1 opiates, correct?

2 A. I thought our first paper -- like I said, I  
3 did not get a chance to look -- broke down illicit of  
4 versus legal when we looked at short-acting versus  
5 long-acting, but I would have to go back to that.

6 Q. Okay. But within licit use, it didn't break  
7 it up by MAT versus other use, correct?

8 A. Not that I am aware of without going back and  
9 reviewing our original paper that I broke it down, but  
10 I would have to look at how we broke it down in the  
11 table.

12 Q. So if we talk about it here in terms of  
13 opinions you're going to offer about the percentage of  
14 NAS births in Ohio in general, the nation in general,  
15 or Cuyahoga and Summit, in particular: Do you have  
16 the ability to say which portion of those relate to  
17 MAT?

18 A. Those would fall in the long-acting.

19 Q. Okay. So what percentage is that, do you  
20 think?

21 A. I would have to look at our paper.

22 Q. What about the percentage that are completely  
23 illicit use?

24 A. I think our first paper stated 33 percent. I  
25 would have to look back at it.

1 Q. What about nonMAT legal use of a prescription  
2 opioid, do you know what percentage those would be?

3 A. I don't know off the top of my head.

4 Now, to expand on that, though, we are -- and  
5 this might have gone back to your very first question  
6 about stuff that is pending that just triggered my  
7 mind.

8 Another grant that has not been signed  
9 officially is looking at universal testing and  
10 breaking it down by all of those differences that you  
11 are describing. So that information -- that study  
12 should be implemented in -- assuming that the  
13 signatures get through -- in August.

14 Q. Okay. And do you have any idea when that  
15 research will be complete?

16 A. It's a two-month study.

17 Q. So do you intend to testify at trial about  
18 the results of that study?

19 A. We should have the information available, and  
20 hopefully submitted for analysis. I'm not sure if we  
21 will have it, but we will -- it is all pending on when  
22 we have those final analysis.

23 Q. They -- they won't have been published yet?

24 A. Correct.

25 Q. Okay. And your -- the way you're drawing

1 line is: You're not going to opine on it based upon  
2 data unless it has been published or is otherwise  
3 publicly available, correct?

4 MS. KEARSE: Object to form.

5 A. Correct.

6 Q. So the specific drugs among the various the  
7 various prescription drugs, regardless of how they're  
8 obtained, do you have any ability to say which  
9 percentage of the available prescription drugs  
10 contribute to NAS in some form or fashion?

11 A. I am not able to do it at this point.

12 Q. And maybe just focusing on some of the big  
13 categories. Like heroin: Do we know which portion of  
14 the NAS offspring that you were able to track and  
15 opine on are related to heroin use?

16 A. I think that is in that third of illicit.

17 Q. And for some portion of the MAT because they  
18 may be using heroin before they got to the medically  
19 assisted therapy?

20 A. No. The MAT would be separate. So out of  
21 that two-thirds that is not illicit, I would say  
22 two-thirds of that is probably MAT.

23 Q. Okay. All right. So, you think that  
24 somewhere around, what, a sixth of the total is  
25 prescription use that is not MAT?



1 A. That sounds about correct.

2 Q. And then for the two -- the four-ninths, give  
3 or take, of the total that is MAT, you think that  
4 those people before they got to MAT will have been  
5 using various drugs illegally, including heroin?

6 MS. KEARSE: Object to form. Misstates his  
7 testimony.

8 A. Yeah. I think the literature would suggest  
9 that they have all had prescription opioids that would  
10 then lead to illicit use of other substances that  
11 would then get them to that.

12 Q. What do you mean, the literature suggests all  
13 have had that?

14 A. So the NIH states that 80 percent of people  
15 that use heroin have started with a prescription  
16 opioid.

17 Q. So what the data actually says is that they  
18 have had some prescription drug in their past, as  
19 opposed to what they started with.

20 Those are different, right?

21 A. So they have had prescription use prior to,  
22 correct.

23 Q. Right. Not necessarily that the prescription  
24 use is what led to some drug -- there could be ten  
25 years in between them and they would be counted as a

1 prior prescriptions, right?

2 MS. KEARSE: Object to form.

3 A. I'm not sure about the timing interval on  
4 that data.

5 Q. When you say 80 percent, you're not trying to  
6 say that 80 percent actually became addicted because  
7 of prescription as opposed to it's just something at  
8 some point in their history that's been documented?

9 MS. KEARSE: Object to form.

10 A. I don't know if that is correlated.

11 Q. Okay. So for like any of the work that you  
12 are doing now through OPQC, when you look at the issue  
13 of use of prescription drugs at some point in the  
14 past, are you using any state databases like the OARRS  
15 database?

16 A. We do that on an individual basis.

17 Q. Okay. Is there some written protocol for  
18 doing that for when you check OARRS or when you do  
19 other investigation to try to figure out what the --  
20 what prescription history the patient has?

21 A. We do that as part of our safety assessment  
22 when we are trying to see if there is a prescription  
23 opioid in -- the mother states that they had a  
24 prescription opioid, we do an OARRS report to see if  
25 that is, in fact, correct.

1 Q. And so even if somebody pops up as having  
2 received a prescription opioid through a prescription  
3 as you figure out on OARRS, that doesn't mean that  
4 they're not also getting illegal drugs or getting  
5 prescription drugs in some illegal fashion, correct?

6 A. Correct.

7 Q. In fact, when you go to OARRS, did you ever  
8 see that sometimes people have more than one  
9 prescription from different doctors at the same  
10 time?

11 A. Yes.

12 Q. Even though that's the whole point of what  
13 OARRS is supposed to prevent, right?

14 MS. KEARSE: Object to form.

15 A. Well, it goes back in the history, so, yeah,  
16 I mean --

17 Q. Okay. So have you heard of the concept of  
18 medically appropriate use of an opioid or medically  
19 necessary use of an opioid?

20 A. Yes.

21 Q. Do you know what percentage of the NAS babies  
22 result from medically appropriate use outside of  
23 MAT?

24 A. That would be the one-sixth that we came up  
25 previously.

1 Q. And it's your view that if they were getting  
2 a prescription for an opioid, that would be medically  
3 appropriate use?

4 A. If they're using it per the prescription,  
5 which we -- so when we say there is a prescribed  
6 opioid, it is hard to know if it is illicit versus  
7 licit.

8 Q. Do you know what percentage of the patients  
9 who have legal prescription for an opioid are then  
10 abusing it in some form or fashion?

11 A. So I would say that more of the babies we see  
12 with short-acting opioids are using it illicitly.

13 Q. Okay. So --

14 A. If their baby is treated for NAS.

15 Q. Right. So less than one-sixth then of the  
16 total NAS population are going to be people who are  
17 getting heavy prescription for an opioid and are  
18 actually using it according to doctor's instructions  
19 without abuse outside of the MAT context?

20 A. Yes. So I think that number would probably  
21 drop down to one-tenth or something like that.

22 Q. Okay. So 90 plus percent of the NAS babies  
23 then are going to result from some form of medically  
24 inappropriate use either current or in the past?

25 MS. KEARSE: Object to form.

1           A. That's the assumption for the MAT, which is  
2   your biggest block, you would be making that  
3   assumption.

4           Q. You think that is a founded assumption based  
5   on the information that you have?

6           A. That most people on MAT have misused  
7   prescription opioids?

8           Q. Have taken and misused --

9           A. Yes.

10          Q. -- opioids or only taken illicit opioids.

11          A. So I think that the majority of people on MAT  
12   have used -- are from -- they're on MAT due to a  
13   substance use disorder, which would be from opioid  
14   use, previous opioid use.

15          Q. Okay. So you think it is a well-founded  
16   statement to say that more than 90 percent of the NAS  
17   cases that you are aware of result from some degree of  
18   medically inappropriate or illegal use, currently or  
19   in the past?

20                 MS. KEARSE: Object to form. Asked and  
21   answered. Misstates his testimony.

22          A. I would state that MAT is the biggest group  
23   of that. So you would have to group that into the  
24   suggestion that there had been previous use or misuse.  
25   I don't know how the percentage of people that got

1 onto MAT with their opioid previous history is.

2 Q. Do you have any reason to believe that it  
3 would be different than what the data is on MAT use in  
4 general?

5 A. No.

6 Q. Okay. So if the data is: The vast majority  
7 of patients who ever end up in MAT use -- getting MAT  
8 have an opiate use disorder -- I'm sorry, a drug abuse  
9 disorder that relates to illicit drug use or improper  
10 medically inappropriate use of prescription opioids,  
11 then that would make sense that we are looking at  
12 about 90 percent of the NAS cases that you see and  
13 that you believe exist, including in Cuyahoga and  
14 Summit County, are resulting from current or past  
15 medically inappropriate or illegal use of opioids?

16 MS. KEARSE: Object to form. Misstates his  
17 testimony.

18 A. I think inappropriate would be a better word  
19 than inappropriate use of opioids.

20 Q. Okay. And so for tracking this in terms of  
21 the data here and the need for intervention, the vast  
22 majority of the -- what is seen as an increase in NAS  
23 over time then is going to relate to this  
24 inappropriate use of opioids, including street drugs,  
25 correct?

1           A. The increase in NAS is directory related to  
2 the increased use of opioids.

3           Q. Which you're saying 90 percent of that is  
4 going to be inappropriate current or past use --

5           MS. KEARSE: Objection to form.

6           Q. -- on a patient-by-patient basis?

7           A. Not -- I don't consider MAT to be  
8 inappropriate use.

9           Q. No, no. Because we about how they get to  
10 MAT. I'm putting that together, right?

11           So if 90 percent of the opioid -- of the NAS  
12 babies have mothers who have at least some point in  
13 the past inappropriate use of opioids -- that's your  
14 testimony so far -- then you would say that that's the  
15 same thing for the increase of opioid of NAS --

16           MS. KEARSE: Object to form.

17           Q. -- in Ohio, including Cuyahoga and Summit  
18 County, relates to inappropriate use?

19           MS. KEARSE: Object to form.

20           A. Like I said, that 90 percent is an estimate,  
21 which I don't have any basis to really go on to that  
22 besides --

23           Q. Besides logic, and we've talked about that?

24           MS. KEARSE: Objection. Argumentative.

25           A. I don't know if I would use the word logic,

1 but estimates.

2 Q. And your -- the current research you're aware  
3 of, including the Voyager databases cut don't allow  
4 you to provide more precise estimate about the  
5 percentage that result from inappropriate use?

6 MS. KEARSE: Objection.

7 A. That is correct.

8 Q. So I had asked about information on the  
9 defendants, and you said you remember two of the  
10 defendants just by their name.

11 Have you had personal dealings with either of  
12 those defendants you remembered by name?

13 A. No.

14 Q. Did you ask, in connection with preparing  
15 your opinions, to get any data or information or  
16 studies, anything that you didn't get?

17 A. No.

18 Q. Have you looked at the expert reports of any  
19 other expert in the litigation?

20 A. No.

21 Q. Have you talked to any of the other experts  
22 in the litigation?

23 A. No.

24 Q. Have you met with anybody other than the  
25 plaintiffs' lawyers?



1           A.   No.

2           Q.   Have you, in connection with your opinions in  
3   this case, reviewed any labels for any prescription  
4   opioid?

5           A.   No.

6           Q.   Have you ever read the labels for any  
7   prescription opioid? And by "label" I mean like the  
8   prescribing information.

9           A.   I have looked at the black box on  
10   methadone.

11          Q.   Is that it? That's the only time you've ever  
12   looked at one of those?

13          A.   Yes.

14          Q.   So how many of them have you prescribed  
15   total, methadone?

16          A.   Morphine and buprenorphine.

17          Q.   Okay. And so for two of the drugs that you  
18   prescribe on a regular basis, you've never even read  
19   their labels?

20          A.   Correct.

21          Q.   And I'm going to go through some things that  
22   I think we have a largely covered, or I think we have  
23   a pretty good understanding of things that you're not  
24   covering. And I hope to just kind of go through them  
25   quickly. Frankly, I'm just telling you this so we can

1 get a little more to the meat, but I think we have  
2 identified kind of the parameters of your opinions.

3 So, as I understand --

4 MS. KEARSE: Objection. Form.

5 Q. -- it based upon --

6 MR. ALEXANDER: That was just a predicate. I  
7 haven't asked a question yet.

8 MS. KEARSE: I know, but I think the record  
9 reflects all the testimony today, but go ahead.

10 MR. ALEXANDER: Okay.

11 Q. You're not offering any opinions as to the  
12 cause of the opioid or opiate crisis or epidemic in  
13 Ohio, correct?

14 A. I think that is debatable.

15 Q. Debatable whether you're offering opinions on  
16 that?

17 A. I think it might fall into this.

18 Q. Well, so do you have some particular analysis  
19 or expertise that allows you to talk about why it is  
20 over the time period when we saw that the  
21 prescriptions were rising and that the usage levels  
22 were prescribed rising, that all of that was  
23 happening?

24 A. So I think that there is a direct correlation  
25 with the increase prescriptions that were out there

1 with the increased rate of NAS.

2 Q. Okay. So do you know why the prescription  
3 rate was increasing?

4 A. No.

5 Q. Okay. Do you know anything about medical  
6 standards in terms of prescribing opioids for pain  
7 management and how those changed over time or any  
8 other factors that led to changes in prescribing  
9 practices?

10 A. Yes.

11 Q. Do you know about that outside of the area of  
12 pediatrics?

13 A. Yes.

14 Q. Okay. Is that something that you have done  
15 for purposes of becoming an expert in this case?

16 A. It's part of the general Ohio legislature for  
17 all physicians.

18 Q. Okay. So you know that there was a time when  
19 there was a change in how things were done for pain in  
20 Ohio?

21 A. For prescriptions -- opioids, yes.

22 Q. Yeah. What is your history there? What is  
23 the time frame that you are talking about?

24 A. So in 2012, there was a mandate to decrease  
25 the number and length of prescription opioids that was

1 enacted.

2 And then there has also been changes more  
3 recently about who can prescribe buprenorphine and  
4 then there's also been legislative -- or mandates  
5 about how many patients a buprenorphine provider can  
6 have.

7 So those are all legislative impacts that  
8 have been discussed as part of this -- these -- our  
9 projects.

10 Q. What about when it started? Were there  
11 legislative efforts or changes across the state that  
12 led to the increase prior to 2012?

13 A. Not that I'm aware of.

14 Q. Do you know anything about national standards  
15 and how they might have changed over time leading to  
16 some increase in prescribing?

17 A. I know that the attorney general -- not --  
18 Surgeon General had come out with a statement also for  
19 national and then CDC also had statements in 2013  
20 about guidelines for prescribing opioids.

21 Q. What about before then? Like back in like  
22 the mid-2000s or early 2000s?

23 A. I'm not aware of anything before 2012.

24 Q. Do you know when the opioid crisis started?

25 A. Going back, it looks like after -- 1999 is

1     when we started to see the increase in prescription  
2     opioids.

3             Q.   Are you going to talk about why that  
4     happened?

5             A.   If asked.

6             Q.   Do you have an opinion to a reasonable degree  
7     of medical certainty as to why it was that there was  
8     an increase in that time period?

9             A.   I only know from the inpatient side that  
10    that's when the fifth vital sign occurred for pain  
11    management within the hospitals, and that seems to be  
12    exactly when that was implicated.

13            Besides that, that would be the only thing  
14    that I would be able to attribute.

15            Q.   So, other than the prescription side, what  
16    about like the illicit drug side? Do you know  
17    anything about trends of heroin use and fentanyl  
18    analogs or any other street drugs, how those have come  
19    or gone or what their drivers have been over the last,  
20    let's say, 15 years?

21            A.   I think we have a good idea about why in the  
22    last four years that it has been increasing, or five  
23    years.

24            Q.   And what are you talking about?

25            A.   As the prescription opioids decreased is when

1 we are seeing the exact increase of the heroin and the  
2 fentanyl.

3 Q. Do you know any other changes in terms of  
4 like what is going on or what has gone on with cartel  
5 activity or importation of illegal drugs from China  
6 that involve, you know, designer drugs, to get around  
7 like DA limits on drugs?

8 Do you know anything about any of that?

9 A. Not outside of what I read on CNN.

10 Q. So is that expert opinion or is that just  
11 educated consumer?

12 A. I don't know -- I would not be an expert on  
13 cartel or Chinese manufacturing of fentanyl.

14 Q. So other than saying in general you know  
15 there was a time when the prescription -- the levels  
16 of prescriptions in Ohio and the country went up, do  
17 you have anything else to say about the cause of the  
18 opioid or opiate crisis?

19 MS. KEARSE: Object to form.

20 A. No.

21 Q. Do you know -- well, do you intend to offer  
22 -- let me ask this way: As I understand it, you don't  
23 intend to offer any opinions as to the percentage of  
24 harms in terms of NAS or any maternal-fetal issues  
25 that relate solely to medically unnecessary

1     prescriptions of opioids?

2                   MS. KEARSE:   Object to form.

3           A.   Did you mean to ask it as a double negative,  
4   or no?   Because I think you did.

5           Q.   I think I did.

6           A.   Okay.   So I --

7           Q.   You don't intend to offer any opinions as to  
8   the harm that was attributed to the medically  
9   unnecessary prescription of opioids?

10                  MS. KEARSE:   Object to form.

11           A.   Medically unnecessary?

12           Q.   Yeah.   Like -- so, every prescription that  
13   got written and filled, there were healthcare  
14   providers writing a script and then some pharmacy  
15   filling it or some other way that it got dispensed.

16                  Is that fair so far?

17           A.   That is correct.

18           Q.   Are you offering any opinions about the  
19   conduct of any doctors or pharmacists or other people  
20   in the healthcare chain that led to any particular  
21   prescriptions being written and filled?

22           A.   So I think one of the problems was there were  
23   some many prescriptions filled that people had extra,  
24   and then there was misuse based on the extra unused  
25   pills.   So I don't know if that would fall into this

1 category or not.

2 Q. Are you critical of other doctors or other  
3 healthcare providers for writing prescriptions and  
4 filling prescriptions that you think weren't  
5 appropriate?

6 A. I think that was done.

7 Q. Do you have some expert opinions and a basis  
8 to offer an opinion about how often that was done or  
9 how much a part of the problem it was here?

10 A. I couldn't give you the numbers or  
11 percentages, but I can just tell you -- I just know  
12 the data that shows the unintentional overdose from  
13 prescription opioids increased. So that would be the  
14 only then I would feel comfortable talking about.

15 Q. So your belief is that doctors bear some of  
16 the responsibility for writing medically unnecessary  
17 prescriptions?

18 MS. KEARSE: Object to form.

19 A. I think the education wasn't there to inform  
20 people or it was just not known at that time.

21 Q. So is that a yes: You think doctors bear  
22 some of the responsibility?

23 MS. KEARSE: Object to form.

24 A. Yes.

25 Q. And do you intend to offer any opinions about



1 the percentage of responsibility that goes on doctors  
2 across Ohio for writing medically unnecessary  
3 prescriptions?

4 MS. KEARSE: Object to form.

5 A. I would have no idea to -- how to quantify  
6 that.

7 Q. And you can't do that for Cuyahoga County or  
8 Summit County either, can you?

9 A. There would be no difference.

10 Q. And what about any like individual, you know,  
11 small nondefendant pharmacies or any particular  
12 pharmacists who maybe have lost their license or gone  
13 to jail over the years for conduct in relation to  
14 dispensing controlled substances? Are you aware of  
15 anything about that?

16 A. I am aware of that.

17 Q. Do you think those folks bear some fault?

18 MS. KEARSE: Object to form.

19 A. Yes.

20 Q. And you haven't formed any opinion about  
21 percentage of fault attributable to that sort of  
22 conduct in terms of the opioid crisis in Cuyahoga  
23 County or Summit County, correct?

24 A. Correct.

25 Q. You don't intend to offer any opinions as to

1 any expenses that have actually been incurred by  
2 Cuyahoga or Summit County that are attributed to  
3 anything about the opioid crisis, correct?

4 A. I think in our report we put the attributed  
5 accounts due to NAS in there -- or is that Ohio -- I  
6 would have to look back at my report if it was  
7 generalized to Ohio rates or if it was county-specific  
8 rates.

9 Q. So there is a general thing about the --  
10 basically hospital costs paid by somebody relating to  
11 NAS stays over a period of time.

12 Is that what you're talking about?

13 A. Yes.

14 Q. Okay. And so as we have talked about, most  
15 of these are paid by Medicaid, correct?

16 A. Yes.

17 Q. So that's not paid by Cuyahoga or Summit  
18 County, correct?

19 A. From their insurance? It is paid by  
20 Medicaid, statewide.

21 Q. Right. Okay. So, is there any opinion that  
22 you intend to offer about any expenses that Cuyahoga  
23 County or Summit Count have actually already incurred  
24 because of anything related to opioids?

25 A. It would just be NAS-related.

1 Q. And as we said, that is not actually a  
2 Cuyahoga or Summit expense, correct?

3 MS. KEARSE: Object to form.

4 A. Just the hospitals in those counties.

5 Q. And they get paid by?

6 A. Medicaid.

7 Q. Medicaid almost 90 percent and private  
8 insurers most of the rest, correct?

9 A. Correct.

10 MS. KEARSE: Object to form.

11 Q. So putting it together: You're not opining  
12 that Cuyahoga or Summit have actually incurred any  
13 specific additional expenses or costs because of  
14 anything relating to the opioid crisis, correct?

15 MS. KEARSE: Object to form.

16 A. I think the whole opioid epidemic has had a  
17 large impact with loss of jobs, increased  
18 incarceration. So I think the impact, even though  
19 outside of my expertise, that there has been an  
20 impact.

21 Q. So that whole thing you just said was outside  
22 of your expertise, correct?

23 A. Most -- the financial aspect, yes. But the  
24 other aspect, I think would fall.

25 Q. Okay. I mean, at trial, do you intend to

1 offer any opinions within your area of expertise about  
2 anything relating to expenses incurred or that will be  
3 incurred by Cuyahoga or Summit County?

4 MS. KEARSE: Object to form.

5 A. No.

6 Q. Okay. Your opinion is that the increase of  
7 NAS in Ohio is multifactorial, correct?

8 MS. KEARSE: Object to form.

9 A. Correct.

10 Q. Can you list all of the factors that you  
11 think should be accounted for in connection with  
12 that?

13 A. I think it is in the report. So I might miss  
14 one or two. But it is multi-factorial. It's based on  
15 there is mom factors, there is genetic factors, there  
16 is infant factors, there is exposure factors.

17 So, it is like I -- like you said, it's  
18 multi-factorial.

19 Q. Yeah. I think actually you didn't list them,  
20 you just use the word multi-factorial in paragraph 42  
21 of your report.

22 A. Okay.

23 Q. But I want to make sure that we just don't  
24 have shorthand for what all of those are.

25 I'm going to guess -- let me talk about a

1 specific section of the report. I've marked as  
2 deposition Exhibit 1 a copy of a report.

3 It says, In Re: National Prescription Opiate  
4 Litigation, MDL No. 2804. Scott L. Wexelblatt, MD  
5 Expert Report, March 25, 2019.

6 (AmerisourceBergen-Wexelblatt-001 was marked  
7 for identification.)

8 Q. So I didn't attach -- and this will be  
9 separate, your CV and whatever -- there were some  
10 attachments, and those will be separate.

11 So paragraph 42 is where we are. And just to  
12 orient, Exhibit 1 is what we have been referring to  
13 as your report, correct?

14 A. Yes.

15 Q. And if you look on the last numbered page,  
16 page 25, is that your signature from March 25, 2019?

17 A. That is a computer generated, yes.

18 Q. Okay. How long before then had you started  
19 your work on this report?

20 A. I first met with plaintiffs' attorneys in  
21 December, I think.

22 Q. Do you know how many total hours you spent  
23 preparing the report and other work that you did prior  
24 to signing it?

25 A. It was 15 hours.

1 Q. Okay. So your \$650 an hour rate you billed  
2 them about \$10,000 worth of time?

3 A. It was under that, correct.

4 Q. What about additional time since March 25, do  
5 you know how much you've spent?

6 A. Since this report, I think we are at eight  
7 hours right now, eight-ish.

8 Q. Are you counting since we got started here  
9 today?

10 A. No.

11 Q. Okay. All right. So what I was just asking  
12 you about is paragraph 42, which is at the bottom of  
13 page 16 of your report.

14 A. So if you -- we have a diagram we posted in  
15 our article, Neonatal Abstinence, An Overview.

16 An article in my CV called Neonatal  
17 Abstinence, An Overview, which we have a table that  
18 lists the multifactorial reasons for NAS. And I would  
19 refer to that for the list of nine things that we  
20 refer to.

21 Q. Okay. Maybe we will have time to pull that  
22 one out. I have it.

23 A. Okay.

24 Q. Do you have anything to add to that list that  
25 is in that publication?

1           A. Okay. So, since that time, I think we have  
2    -- the big boxes are probably the same, but there has  
3    been -- since that publication, I think hospital sites  
4    are -- there is more and more literature supporting  
5    different aspects that it may have been misstated in  
6    that paper, which was 2018.

7           Q. So not all women who give birth after taking  
8    some degree of opioid or opiate while pregnant have a  
9    baby who will ultimately be diagnosed as having NAS,  
10   correct?

11          A. So we define NAS in our statewide  
12   collaborative as those that need pharmacologic  
13   treatment. So only 40 to 30 percent will meet that  
14   definition of having NAS. The others we would  
15   classify as opioid exposed.

16          Q. And so, we have seen different estimates of  
17   the range of the -- of the NAS babies who require  
18   pharmacologic intervention, but from the data track  
19   that you have from OPQC, it is running around 40  
20   percent?

21                 MS. KEARSE: Object to form.

22          A. Forty-two percent, correct.

23          Q. And you think that is an accurate percentage  
24   based upon the diagnosis criteria that you are  
25   using?

1 A. I know that's accurate, correct.

2 Q. And then the rest of them -- is there some  
3 percentage that will exhibit symptoms but not require  
4 pharmacologic intervention?

5 A. Yes.

6 Q. What percentage of opioid exposed infants is  
7 that?

8 A. So I would say the majority of babies that  
9 are opioid exposed show signs and symptoms, they just  
10 don't need pharmacologic treatment.

11 Q. What about where the exposure is in like the  
12 first trimester but there's nothing the remaining  
13 trimesters?

14 A. Then that would be even less.

15 Q. Is there data on that about the timing and  
16 extent of exposure --

17 A. There is.

18 Q. -- as relate to the incidents?

19 A. Yes.

20 Q. Is it, in general, the more that's used, the  
21 later it is in the pregnancy, the more likely there  
22 are to be signs and symptoms of withdrawal?

23 A. So there's two things that have been looked  
24 at. The -- the duration, meaning more than 90 days,  
25 versus under 90 days, and then timing within 30 days



1 of delivery versus longer than 30 days.

2 Q. Okay. And you're not opining to a reasonable  
3 degree of medical certainty that the drugs we're  
4 talking about, the opioids, particularly the  
5 prescription opioids, have teratogenic effects,  
6 correct?

7 A. Teratogenic, we know that they may be  
8 associated with long-term outcomes, so we are not  
9 really understanding the pathway. So if you use the  
10 true definition of teratogenic, I couldn't -- I  
11 wouldn't say a hundred percent, no, we don't know the  
12 pathway of why we're having babies with strabismus  
13 that are opioid exposed.

14 Q. So sitting here today, you can't opine to a  
15 reasonable degree of medical certainty that there are,  
16 in fact, teratogenic effects of the prescription  
17 opioids, correct?

18 MS. KEARSE: Object to form.

19 A. I would not -- I would say if we are  
20 considering strabismus as part of teratogenic effect,  
21 I would have to look at the true definition of what  
22 that would mean. So at this point, I would not be  
23 able to give you a true answer.

24 Q. And other than that, setting aside the  
25 strabismus, you're not aware of any other possible

1 effect that would be considered teratogenic or  
2 iatrogenic, I guess, too?

3 A. Are outcomes, I think that would be the one  
4 that I would have to look at the definition of  
5 teratogenic to link it to.

6 Q. So do you intend to offer any opinions at  
7 trial that there were other nonparties in this case,  
8 other than prescribing doctors and individual nonchain  
9 pharmacies and pharmacists, who you think bear some  
10 responsibility for the opioid crisis in Ohio?

11 MS. KEARSE: Object to form. Misstates his  
12 testimony.

13 A. No.

14 Q. Well are there other third parties where you  
15 think that they should have done more to help minimize  
16 the effects on NAS babies and improving maternal  
17 outcomes?

18 A. I need to get more clarification on what you  
19 mean by that.

20 Q. Sure. So in other words, do you intend to --  
21 well, let me ask it this way: So, you've identified,  
22 and we've gone over this in general terms, that there  
23 are additional things that you think should be done to  
24 try to address NAS, correct?

25 A. Yes.

1 Q. And we can look at what has been done in  
2 terms of the timing of implementing various changes or  
3 protocols in hospitals in Cuyahoga and Summit County,  
4 correct?

5 A. We can go back?

6 Q. We could look at the timing and see when  
7 anybody implemented some additional measures or  
8 considered them and didn't implement them, right?

9 A. Yes, that would be possible.

10 Q. So do you intend to opine that the  
11 third-parties who maybe could have done more to help  
12 minimize the effects of NAS have done all that they  
13 could have?

14 MS. KEARSE: Object to form.

15 A. The third-parties being?

16 Q. Hospitals and healthcare providers, and  
17 anybody else who you have ultimately identified as  
18 maybe needing some sort of push to do better going  
19 forward.

20 A. That I would state?

21 Q. Let me -- the various third-parties, the  
22 hospital, the doctors, all of that, I asked you about  
23 whether there is some nonparties who bear fault for  
24 creating the opioid crisis, right?

25 Now what I'm asking about it: Do you

1 criticize or do you intend to testify that they did  
2 everything right, any of these third-parties in terms  
3 of taking steps to minimize the effects of the opioid  
4 crisis?

5 MS. KEARSE: Object to form.

6 A. So I think that what we lay out is the gold  
7 standard and what we want to be implemented, and it's  
8 not always able to be done due to resources.

9 So I don't think it's -- critical is a tough  
10 word to use because there may not have been resources  
11 to implement some of these protocols or suggestions.

12 Q. Do you know anything about what resources  
13 existed at various time in Cuyahoga or Summit County  
14 to initiate any additional measures to address NAS?

15 A. So we have worked on that since 2012 in all  
16 of those counties.

17 Q. Do you, sitting here today, know what  
18 resources were available in terms of financial  
19 resources, staffing, anything else you might have  
20 needed as a resource to make any of these changes  
21 happen over the last seven years?

22 A. Specific staffing issues, no, I wouldn't even  
23 know in our region.

24 Q. What about money in the budgets?

25 A. No.

1           Q. Now, one of the things that you said in your  
2   report that you were not going to address was the  
3   issue of child maltreatment.

4           What does that mean: child maltreatment?

5           A. I would have to see where you're referring  
6   that to. You said in the report. I -- can you show  
7   me where in the report?

8           Q. Probably not fast, but I'll just ask it.

9           So when you talk about the impact of maternal  
10   use, you're talking about in terms of essentially  
11   creating opioid exposure in utero that can result in  
12   NAS or -- NAS or the need for additional treatment for  
13   opioid exposure that doesn't result in a diagnosis of  
14   NAS, correct?

15          A. You're stating that NAS -- opioid exposure  
16   doesn't always lead to NAS. Is that what you just  
17   stated?

18          Q. Well, that's part of what you said, right?

19          A. Yes. I'm stating that.

20          Q. Okay.

21          A. I guess I don't know what you're asking right  
22   now.

23          Q. The focus of your report is on the need to  
24   take steps to address essentially the impacts of use  
25   by pregnant women of opioids that results in either

1 NAS or having children born who had opioid exposure in  
2 utero, correct?

3 A. That's what this report is about, yes.

4 Q. What you are not addressing are other effects  
5 on child care or child health from a mother using  
6 opioids, including illicit opioids and street drugs  
7 when she's not pregnant, like when he's raising the  
8 child, correct?

9 A. This report is basically on women of  
10 childbearing age and pregnant women, yes.

11 Q. But not women of childbearing age when  
12 they're not pregnant?

13 You're not offering any kind of testimony  
14 about the impact in any direction of whether women who  
15 are abusing opioids, including, you know, illicit  
16 drugs, create other social services needs or  
17 healthcare costs or otherwise negatively impact the  
18 lives of their children because of their abuse?

19 A. No, because we know that, as you mentioned  
20 earlier, which I agreed to, was that we know that  
21 using the illicit opioid use does lead to  
22 unintentional pregnancies. So you'd have to address  
23 it as a whole pregnant age of -- childbearing age.

24 Q. So is that the only area where you're talking  
25 about use by a woman outside of pregnancy?

1 A. Childbearing age, correct.

2 Q. But in terms of leading to unintended  
3 pregnancies?

4 A. Correct.

5 Q. Are you going to say anything about other  
6 healthcare risks to the mother or other impacts on the  
7 child of a mother being somebody who has an opioid use  
8 disorder or is otherwise abusing opioids or street  
9 drugs?

10 A. Yes.

11 Q. What else are you going to testify about?

12 A. The increased risk of hepatitis C.

13 Q. That's on the paper when it comes out that we  
14 don't have yet?

15 A. Correct, but I think there is an overwhelming  
16 amount of evidence out there about the hepatitis C  
17 increases that are out there from the CDC.

18 Q. So what are you doing to treat hepatitis C in  
19 some portion of children who have it because their  
20 mothers were drug abusers?

21 A. So there is a new drug that is out there now  
22 for pediatric use that -- so, now, the process that we  
23 are doing is we're testing kids. The earliest we can  
24 test a toddler is at 18 months, and then the earliest  
25 we can treat them is between two and three years of

1 age based on what drug the GI, hepatologist think is  
2 the best for that case. So we refer -- our job is to  
3 identify and then refer to the hepatologist.

4 Q. What is the drug?

5 A. I think there is a new one, and I don't know  
6 if it's -- I am not a hundred percent sure of the  
7 indications of what are the new FDA regulations on the  
8 drug and what the new trials are out there because it  
9 is changing.

10 Q. Do you know the name?

11 A. I -- I wouldn't -- I don't know off the top.  
12 It's R-I-B-O and then something something something  
13 something.

14 Q. Clearly, you haven't prescribed that one  
15 yet?

16 A. No, I will not prescribe that.

17 Q. Okay. And you don't intend to offer opinions  
18 at trial about the public health impact or the burden  
19 on social services of anything relating to alcohol  
20 abuse, correct?

21 A. Not related to alcohol abuse.

22 Q. Including concomitant alcohol abuse during  
23 pregnancy in woman who are also abusing opioids;  
24 that's not something you are going to talk about, are  
25 you?



1 MS. KEARSE: Object to form.

2 A. That would fall under polysubstance abuse,  
3 opioid use, so I think that would fall under that.

4 Q. Okay. And what is your best estimate or what  
5 opinion can you offer about the percentage of patients  
6 in Ohio who are abusing alcohol while pregnant in  
7 addition to abusing opioids?

8 A. I think our first paper stated that about 9  
9 percent.

10 UNIDENTIFIED SPEAKER: I'm sorry?

11 THE WITNESS: Nine percent for our first  
12 paper.

13 Q. What about alcohol use that falls short of  
14 meeting the criteria for abuse, do you know what that  
15 is?

16 A. Our question was: Was there use. And I  
17 would have to go back to how we -- in our methodology  
18 of what we defined alcohol use, if it was  
19 trimester-related or any use or misuse.

20 Q. Have you ever done any research on fetal  
21 alcohol syndrome?

22 A. No.

23 Q. Have you ever done any research on the  
24 effects of alcohol during pregnancy?

25 A. I have not done research on that.

1 Q. Do you know from your training if alcohol is  
2 teratogenic?

3 A. I know there is long-term outcomes from fetal  
4 alcohol syndrome.

5 Q. And it is considered teratogenic?

6 A. Like I said, the definition, I would have to  
7 look up to see what you define as teratogenic.

8 Q. I mean, there is physiologic manifestations,  
9 not just behavioral, right?

10 A. Correct.

11 Q. Like an actual defined set of things that can  
12 be seen where you have differences from the norm in  
13 terms of facial structure and various other things in  
14 fetal alcohol syndrome, correct?

15 A. Yes.

16 Q. And there are other ways in which alcohol use  
17 is considered teratogenic, correct?

18 A. Yes.

19 Q. And the harm to the infant -- or the -- I'll  
20 say it more accurately.

21 The harm to the fetus from maternal use of  
22 alcohol is because the infant -- uterus sac -- I'm  
23 sorry. Long day.

24 When a women drinks while pregnant, the  
25 alcohol actually directly goes to the bloodstream and

1 affects the fetus, correct?

2 A. It does cross through the placenta.

3 Q. Okay. And the general consensus is that no  
4 amount of alcohol is safe during pregnancy?

5 A. I don't think they have -- I think that the  
6 recommendation is less than one glass per week. I  
7 don't know the exact obstetric recommendations by  
8 ACOG.

9 Q. Do you know when it changes based upon  
10 which --

11 A. Trimester?

12 Q. -- trimester of pregnancy you're in?

13 A. I don't know those recommendation by ACOG.

14 Q. And is it your understanding that the more a  
15 woman drinks during -- of alcohol, not just water, the  
16 more alcohol consumed during pregnancy, the greater  
17 the risk is of adverse effects to the fetus?

18 A. I think it's the amount and duration, the  
19 same as it is with what we are finding with opioids.

20 Q. And do you know what the specific criteria  
21 are for fetal alcohol syndrome?

22 A. It is based on facial features and small for  
23 gestational age are the risk factors for referral.

24 And then once you have developmental delays,  
25 then I think that's when the diagnosis is attached to

1 the child.

2 Q. Okay. And what about increased incidence in  
3 fetal alcohol exposure of poor balance control in the  
4 infant, learning disorders, delayed mental  
5 development, poor memory, problems with impulse  
6 control and other behavioral problems?

7 Are you aware of any of those?

8 MS. KEARSE: Object to form.

9 A. So I know there are delays. So going  
10 through each one, I would have to -- I know there is  
11 global delays. So I would assume if you're reading  
12 off a list, you got it from somewhere.

13 Q. Okay. And these are not time limited  
14 problems as far as you know, that maternal use of  
15 alcohol can lead to life-long issues with the infant  
16 along the lines of what I have outlined?

17 A. I haven't done a lot of research on fetal  
18 alcohol syndrome.

19 Q. So in the research that you are doing now on  
20 opiate exposure during pregnancy, what level of detail  
21 do you have on the amount and duration of alcohol  
22 exposure during pregnancy?

23 A. So that is self-report and obstetric  
24 history.

25 Q. Very inaccurate, right?

1 MS. KEARSE: Object to form.

2 A. Yes. Not "very." It is you underestimated  
3 based on true incidence. If you correlate our other  
4 studies, looking at report versus test.

5 Q. Okay. So I mean if -- you would expect that  
6 some of the data that you have cited from tobacco use  
7 during pregnancy would apply to alcohol as well?

8 That if women are underreporting tobacco use  
9 by a factor of four to six, you would see something  
10 probably similar to alcohol use?

11 A. I don't know about those numbers.

12 Q. Do you expect it is underreported  
13 significantly?

14 A. I wouldn't know about significantly.

15 Q. Well do you expect that it's not just in  
16 terms of what the fact of it, but that there is going  
17 to be underreporting of extent and duration of alcohol  
18 use during pregnancy?

19 A. Do I -- so can you repeat that one more time?

20 Q. Sure. Do you expect that the underreporting  
21 of -- from self-reporting of alcohol use during  
22 pregnancy is going to extend to underreporting the  
23 extent and duration of alcohol use?

24 A. I think, yes, it would underestimate.

25 Q. And so in any of the published papers that

1     you have seen, is there information that allows you to  
2     reliably say how often babies born with NAS also have  
3     more than de minimus alcohol exposure in utero?

4           A. All I know is that in our NAS clinic we don't  
5     see -- it's been a -- we have not had the 9 percent or  
6     whatever percentage that we stated in our first study  
7     of baby with fetal alcohol syndrome and NAS. So  
8     that's the only thing I can tell you, that what we see  
9     with opioid use and alcohol.

10          Q. I just want to make sure I understand what  
11     you're saying.

12                 Do you -- you've seen that 9 percent of NAS  
13     babies also have fetal alcohol syndrome?

14          A. No. That's what I'm saying. We don't see  
15     that.

16                 So on our first paper reported 9 percent of  
17     alcohol use with NAS, but we don't see the amount of  
18     alcohol to cause fetal alcohol syndrome in our NAS  
19     clinic.

20          Q. We can go through them if we need to, but the  
21     recommendations that you have in terms of supportive  
22     services, intervention, education, for, you know,  
23     women of childbearing age, some of these other things,  
24     you, frankly, would include these same sort of  
25     recommendations to try to limit alcohol use during

1 pregnancy, wouldn't you?

2 A. I think majority of these have probably  
3 already been done with alcohol.

4 Q. Okay. So you think they should be done,  
5 right, still?

6 A. Oh, yeah.

7 Q. Okay. Same thing for cocaine: You think  
8 cocaine, a nonopioid -- opiate use during pregnancy  
9 should be discouraged as well through some of these  
10 same measures?

11 A. Yes.

12 Q. Are there any specific measures here other  
13 than how you would treat NAS itself that are different  
14 for discouraging or addressing maternal abuse of other  
15 drugs?

16 A. Yes.

17 Q. Which?

18 A. Yes. So we don't need to have MAT for  
19 cocaine.

20 So when you look at our supportive services,  
21 expanding MAT, the first two are definitely related  
22 towards opioids. Our third one looks like it's  
23 related specifically to opioids, on buprenorphine.

24 Most of the time, we don't need residential  
25 treatment for alcohol, ongoing care. So it looks like

1 most of these -- I can go through each one -- are  
2 opioid specific.

3 But I think the General Education and  
4 Training -- if you go up to B, those would definitely  
5 be for any drug. But I think C is where we get to the  
6 opioid specific.

7 Q. Okay. So, let's -- let's -- maybe we'll do  
8 it this way: If you look at the nine little  
9 checkmarks on page 22 and 23 of your report,  
10 Exhibit 1, under A. Prevention.

11 A. Uh-huh.

12 Q. All nine of those would have -- would apply,  
13 or with slight modification, would apply to other  
14 drugs or alcohol abuse, correct?

15 MS. KEARSE: Object to form.

16 A. I can read it just one each through, if you  
17 like.

18 So the first one about delaying intervals,  
19 pregnancy. Yes.

20 Education. Yes.

21 I think the third one is definitely -- could  
22 be established to opioids or any other substance.

23 THE WITNESS: Sit up. Okay. I was trying to  
24 read it without my readers.

25 Q. When I resume the question, it's more



1 question and answer since you were just given posture  
2 advice.

3 THE REPORTER: I just wanted you to move your  
4 hand away from your mouth.

5 THE WITNESS: Okay.

6 Q. You're now I think at the fourth checkmark on  
7 -- under Prevention on page 22 of your report.

8 A. Yes.

9 Q. The question is whether these relate to  
10 substance abuse in general, including alcohol, or  
11 whether they're just specific to opioid or opiate  
12 abuse.

13 A. So the fifth one, we are -- recommend the  
14 NIDA scale that addresses --

15 Q. You're on the fourth one.

16 A. Okay. The fourth one, provide counseling for  
17 women -- impact of substance use on pregnancy. So  
18 that would be any drug, or all drugs.

19 The fifth one is -- we do focus on. The NIDA  
20 scale is specific for tobacco, alcohol and opioids.  
21 And I think maybe the NIDA addresses illicit, so, yes.

22 Q. You're on the sixth one?

23 A. Yeah. So the bottom -- the last one on  
24 Page 22, Implement programs to improve and expand  
25 screening. Would be all.

1 Q. Page 23, the first one.

2 A. So that is specific for NAS as that deals  
3 with trying to get -- once you define an obstetric  
4 plan with MAT is where you fall into -- that's what --  
5 the comprehensive obstetric team is where we have  
6 found in our statewide collaborative that you need a  
7 team approach to do that.

8 Q. And for other drug abuse during pregnancy,  
9 you don't need a team?

10 A. No. Because like I said, that refers back to  
11 be MAT. So most of -- the problem that we have found  
12 is either addiction specialists don't feel comfortable  
13 taking care of pregnant women and/or obstetrics people  
14 don't feel comfortable writing MAT. So that's why we  
15 run into that team approach.

16 Q. Second bullet on page 23.

17 A. So I think that would -- be you could expand  
18 it to all, that would be great.

19 Q. Third one.

20 A. So that is talking about opioid addiction  
21 specifically. So, I think if you wanted to expand  
22 that to include other drugs, I think that would be  
23 public education. I think it has been out there for  
24 tobacco and alcohol for quite awhile, but if --  
25 you definitely could expand it.

1           Q. I mean, one of the things you see in your  
2 papers is there's still a lot of smoking during  
3 pregnancy, especially in the subset of population that  
4 is poor?

5           A. Correct. So yeah. This would be great for  
6 all.

7           Q. Okay. So for Education and Training, there  
8 are three listed. All three of those education and  
9 training items are ones that you could expand to  
10 address all substance abuse, including alcohol abuse,  
11 right?

12           MS. KEARSE: Object to form.

13           A. I think that the middle one goes back to the  
14 team approach that we are seeing specifically with  
15 MAT.

16           So I would think the first one, for sure, is  
17 generalizable.

18           Screening tools, once again, would go ahead  
19 -- would be generalizable.

20           Q. Well, the second one, it says: Enhance  
21 training for providers caring for pregnant women with  
22 opioid use disorders to understand the complexity of  
23 the woman's social, mental and physical problems.

24           One of the things in some of the literature  
25 that you have written or cited is that it says there

1 are essentially negative attitudes among a lot of  
2 healthcare providers -- and I know this is part of  
3 monthly presentations that the OPQC group does where  
4 they talk about there is a need to improve the  
5 attitudes of healthcare providers that substance abuse  
6 is a disease and they shouldn't blame the mother and  
7 they should consider things like overlays of history  
8 of abuse and trauma and things like that.

9 Have I said that accurately?

10 A. Yes, and that is going to make me want to go  
11 back and say that's our fourth paper under review  
12 right now, too. We are publishing that data.

13 It's already been -- it's in process of being  
14 published.

15 Q. So the beginning when you said there are  
16 three, there are really four?

17 A. There is actually four, now that you brought  
18 it up. I forgot all about that paper, but thanks for  
19 reminding me.

20 Q. And there are two in grant review?

21 A. Yes.

22 Q. Any more?

23 A. I think that's it. You might trigger my  
24 memory, but --

25 Q. So for the fourth paper that is pending

1 publication, it has been submitted but it hasn't been  
2 approved?

3 A. Correct.

4 Q. And do you intend to rely currently on  
5 anything in that particular paper?

6 A. It is talking about exactly what you just  
7 said, how there is negative stigma and how we have  
8 been able to improve that statewide through our OPQC  
9 journey.

10 Q. And that is also generalizable to substance  
11 abuse disorders in mothers?

12 A. No. We just focused on opioid. I think the  
13 questions were -- we really only focused on opioid.

14 Q. The need to enhance training for providers  
15 caring for pregnant women with substance abuse  
16 disorder is to understand the complexity of the  
17 woman's social, mental and physical problems.

18 That is something that you think is true for  
19 all substance abuse disorders, right?

20 MS. KEARSE: Object to form.

21 A. I think the education is out there on tobacco  
22 and alcohol, but we could always do better.

23 Q. What about cocaine and benzodiazepines and  
24 the other drugs that we have seen that are  
25 increasingly prevalent among pregnant woman in Ohio?

1 A. You are correct.

2 Q. So we should improve, through training, the  
3 attitudes of healthcare providers, correct?

4 A. For substance use disorders, correct.

5 Q. Not just opioids?

6 A. Include all substance use disorders.

7 Q. So going through the ones that we just talked  
8 about, taking these measures across the board for  
9 prevention and education and training to address all  
10 substance abuse disorders would have other public  
11 health benefits you believe, right?

12 A. They could.

13 Q. Including that there would be benefits that  
14 would essentially accrue to pregnant women and  
15 potentially others who are not abusing opioids or  
16 opiates, correct?

17 A. If we could decrease other problems  
18 underlying that are not related to opioids, I think  
19 that would be a great thing.

20 Q. So the plan that you are calling for would  
21 have benefits beyond just specifically addressing any  
22 health affects of the opioid crisis?

23 A. If you did any substance use and subtracted  
24 the word opioid use, possibly.

25 Q. Like some of the counseling that is at issue

1     here, I think is going to be -- I think doing things  
2     like reducing unintended pregnancies, that has a lot  
3     of additional public health benefits, right?

4             MS. KEARSE: Object to form.

5             A. Yes.

6             Q. We're not -- that is not just something that  
7     would need to be done because of anything about  
8     opioids or opiates, correct?

9             A. We just know it is higher in the opioid --  
10    women with opioid use, or substance abuse disorder.

11            Q. So in the next category for C, the first  
12    three are specific to opioid abuse, correct?

13            A. So they are regarding MAT, so that would be  
14    just for opioid.

15            Q. And then the fourth one: Provide intensive  
16    support to mothers during pregnancy, etcetera,  
17    including outpatient programs.

18                    That's generalizable for all of the substance  
19    abuse, right?

20            A. No, because most of those don't need ongoing  
21    care outside of the postpartum period. So like our --  
22    so I think during that period is where we see a higher  
23    risk.

24            Q. You mean a "higher risk," of what: Relapse  
25    or suicide or what?

1 A. Overdose, yes. Overdose deaths.

2 Q. Intentional overdose deaths?

3 A. No.

4 MS. KEARSE: Object to form.

5 A. Unintentional.

6 Q. In some of your literature, that's a period  
7 of a high intentional overdose, right? The postpartum  
8 period associated with depression.

9 A. I don't think we -- there is differentiation  
10 between intentional and unintentional. It is just  
11 overdose.

12 Q. Okay. So, the need for additional services  
13 for people with a substance abuse disorder in the  
14 postpartum period, you don't think that's  
15 generalizable to all substance abuse of illicit  
16 substances?

17 A. It is higher in opioid. So we know that the  
18 7- to 12-month mark is the highest incidence of moms  
19 having an unintentional overdose death.

20 So that is different. We don't see that with  
21 cocaine or alcohol or tobacco.

22 Q. Is there a need for additional outpatient  
23 programs for pregnant women who have other types of  
24 substance abuse besides opioids?

25 A. No. I think if you did a safety plan at the



1 time of delivery, you wouldn't need the postpartum  
2 period where that is specific to the opioid  
3 population.

4 Q. Next one says: Implement coordinated care  
5 and connect mothers with outpatient support and  
6 treatment programs prior to discharge.

7 You think that is generalizable to all  
8 substance abuse?

9 A. Once again, I would say that is opioid  
10 specific most of the time because of the -- what we  
11 just stated before, about the ongoing care that we  
12 would see for that first year, if not longer.

13 Q. What about next one: Post -- provide  
14 postpartum long-term addiction care. That's  
15 generalizable?

16 It's the last one on page 23.

17 A. Yeah. I think that goes into -- the way this  
18 is formatted I think that -- is that? So that is just  
19 a stand-alone statement.

20 That long-term addiction is something that  
21 that we see. Most of the time it is ongoing usage  
22 that we see more with opioid addicted women than we  
23 do.

24 So I think that could be transferable to -- I  
25 don't think we think about smoking mothers as having a

1 long-term care needed.

2 So some of it is related probably more to  
3 ongoing use which we see in alcohol and opioids.

4 Q. What about cocaine, benzodiazepines, other  
5 drugs of abuse?

6 A. I think care is always good.

7 Q. Okay. So the need for additional postpartum  
8 long-term addiction care would apply to everything but  
9 smoking, you think?

10 A. I mean, it would be great to get people not  
11 to smoke.

12 Q. Okay. So next one, top of page 24: Provide  
13 aftercare services to mothers so mothers can cope with  
14 their addiction and learn about the special needs of  
15 their infants.

16 Would that apply to any substance abuse that  
17 involves an illicit drug?

18 A. I think it's more -- when we talk about talk  
19 about opioids is knowing that we want to get the  
20 concept across that it is a life-long illness that,  
21 you know, they need continuing care and MAT, whereas  
22 some of the others are -- interventions are just stop  
23 using.

24 Q. Next one: Create additional residential  
25 treatment facilities for both the mother and infant.

1           That's generalizable, right?

2           MS. KEARSE:   Objection.

3           A.   Once again, I don't see we think -- when we  
4   see the care for the mother and the infant dyad  
5   together, it is more of what we see with long-term  
6   care with moms maintaining their MAT for past the  
7   first year.

8           And so that's where this statement was from.  
9   I had not thought about it the way you're addressing  
10   it, but I don't think we would have to have  
11   residential treatment for tobacco use.

12          Q.   Well, I asked you about illicit substances.

13          A.   Illicit, yeah.

14          Q.   So do you know in Cuyahoga or Summit County  
15   what their capacity is in terms of residential  
16   treatment facilities, whether they need more?

17          A.   So most of the -- when we did our MOMS Plus  
18   program that we are doing now through OPQC, each  
19   region is focused on a different model to see if we  
20   can identify the best model of care.

21          And we have found that the resources just are  
22   not there for enough -- or many residential treatment  
23   facilities.   So when I say "additional," it may be  
24   their first.   I'm not sure about their actual  
25   resources in each county in this state.

1           It is -- really what we have been finding is  
2   generalizable. What works in one county -- just  
3   because it's happening in one county, there's no  
4   reason to make any county different in Ohio.

5           Q. Okay. So you can't opine that Cuyahoga or  
6   Summit County need additional residential treatment  
7   facilities for both mother and infant?

8           MS. KEARSE: Objection.

9           A. We know that there is not enough in any of  
10   our counties. So I could tell you that.

11          Q. Do you know the number or a cost or any  
12   details on that -- like that for residential treatment  
13   facility?

14          A. I don't know numbers or cost.

15          Q. Okay. Next one says: Provide family-based  
16   care to opioid exposed children as well as direct care  
17   for parent in recovery or maintenance.

18                 If we changed "opioid exposed" to a broader  
19   definition of substance exposed, would that one apply  
20   more broadly, too?

21          MS. KEARSE: Object to form.

22          A. So the family-based centered care is-- that  
23   sort of incorporates what we have been doing with our  
24   NAS high-risk follow-up clinic, because we have been  
25   seeing that it looks like they need different care if

1     they are opioid exposed.

2                 So I think that's where this would be really  
3     opioid specific because we know that the child has  
4     different needs during their first two years. So that  
5     is why the family-centered care could incorporate the  
6     mom and baby together.

7                 Q. So you said before that your NAS clinic is  
8     one of the few in the country that is doing long-term  
9     follow-up in study.

10                Do you know any other facilities doing  
11     that?

12                A. Yeah. There is one in New Mexico, and I  
13     don't know exactly which hospital they're correlated  
14     to. There is one in Boston and there is one in  
15     Florida.

16                Q. Do you know the names of the Boston or  
17     Florida ones?

18                A. So the Boston one, I think, is with Boston  
19     Medical Center. And the Florida one is the Hopkins  
20     satellite in Tampa.

21                Q. So the next one says, NAS: Nurseries with  
22     standardized evidence-based policies to assess and  
23     treat infants with NAS.

24                Is that generalizable to any broader  
25     substance abuse disorder?

1 A. No.

2 Q. Provide -- the next one: Provide support to  
3 families to improve outcomes for infants with NAS  
4 through breastfeeding, visits, and other support.

5 Some of that is generalizable, right?

6 MS. KEARSE: Object to form.

7 A. No, we wouldn't want somebody with illicit  
8 use to breastfeed.

9 Q. So for like smoking or alcohol, do you  
10 recommend breastfeeding or not?

11 A. For smoking, we -- those are not illicit  
12 substances.

13 Q. That's my question, because I asked you about  
14 substance abuse.

15 This one: Provide support to families to  
16 improve their outcome for infants through  
17 breastfeeding, visits, and other support.

18 That is only for opioids or you can't  
19 generalize that for any substance abuse?

20 MS. KEARSE: Object to form.

21 A. So we wouldn't improve outcomes through  
22 breastfeeding with other substances. So this would be  
23 purely for NAS.

24 Q. What about visits and other support. I mean,  
25 you want to increase parental involvement in all of

1     these kids, right?

2             A.   Even kids that have no exposures.

3             Q.   I mean, one of the things that you see is  
4     that the parental involvement, while the kid is in the  
5     hospital, while the NAS infant is in the hospital is,  
6     on average, relatively low, at about 58 percent of the  
7     visits or the intervals of checks?

8             MS. KEARSE:   Object to form.

9             A.   Actually, there is a study that showed you  
10    can get up to a hundred percent.   The Walkman study  
11    showed that if they to got it up to a hundred percent,  
12    that those babies did better.

13            Q.   They just cut off nine days from their  
14    average length of stay, right?

15            A.   Yes, you're correct.

16            Q.   So I'm talking about the average was about 58  
17    percent, and it -- but they are able to say when you  
18    got a hundred percent, they actually left -- left  
19    earlier and did much better, right?

20            MS. KEARSE:   Object to form.

21            A.   It was a linear.   So 80 percent did better  
22    than 20 percent.   So you could pick any higher number  
23    is going to do better than any lower number.

24            Q.   Right.   So part of what you encourage is the  
25    parents, whether they have opioid use disorders, or

1 some other substance abuse disorder, or nothing, to be  
2 present as much as possible while the baby is in the  
3 hospital?

4 MS. KEARSE: Object to form.

5 A. And the other substances aren't associated  
6 with a longer length of stay, so it doesn't really  
7 help.

8 Q. Okay. Do you have an idea or -- I'm sorry.

9 Do you have opinion as to why it is that the  
10 average is less than 60 percent in terms of parental  
11 involvement throughout the stay of an NAS baby?

12 MS. KEARSE: Object to form.

13 A. I have not practiced in their hospital, so I  
14 couldn't tell you why their data was 60 percent.

15 Q. What's it like at your hospital?

16 A. It varies. So we have some that are there a  
17 hundred percent and we have some that are zero -- that  
18 are there zero percent of the time because of  
19 circumstances.

20 Q. What do you mean by "circumstances"?

21 A. That they are having -- moms have overdosed  
22 in their rooms and have been in the intensive care  
23 unit, so they are not in our unit with their baby.

24 Q. Do you have an understanding of the average  
25 at your hospital over time?



1 A. We haven't looked at that.

2 Q. Is it your impression that the more often the  
3 mother is present the better the baby does for NAS?

4 MS. KEARSE: Object to form.

5 A. We've never looked at it. So I know  
6 Dr. Walkman and I think what they're -- the more a  
7 parent is there the easier it is to implement our  
8 non-pharmacologic bundle. So that would go entail  
9 with improving outcomes. So --

10 Q. So the need to tell parents to be present for  
11 their baby and to encourage support, that's specific  
12 to NAS?

13 A. Correct.

14 Q. And do you have any experience that  
15 encouraging support like that actually yields  
16 benefits.

17 A. Just in her report.

18 Q. Right. So when they had higher  
19 participation, they had better outcomes?

20 A. Right.

21 Q. Question is: Does encouraging it one way or  
22 another actually make the mothers with a drug abuse  
23 diagnosis actually show up more often?

24 A. Yeah, it seems to be. We haven't done any  
25 research, but we know that when we sit down and talk

1 to moms and say, your baby is doing better when you're  
2 here, stay on the couch that we have in the room, they  
3 do it and they listen and it works.

4 Q. And that's a new bit of advice?

5 A. The meta-analysis just came out in the last  
6 six, maybe 12 months, looking at rooming in to show  
7 that it was, has improved care.

8 Q. And which paper is that?

9 A. It was a meta-analysis that came out, and I  
10 would have to refer to my PowerPoint talk that was  
11 just done in the past 12 months.

12 Q. There is a rooming in paper that you cited?

13 A. So there is a meta-analysis rooming in paper  
14 that I cite in my most recent talk.

15 Q. And so a meta-analysis takes multiple studies  
16 and kind of combines them in some statistically  
17 appropriate, you would hope, way to come to  
18 conclusions and essentially provide higher power to  
19 evaluate specific outcomes or end points?

20 A. That's a --

21 MS. KEARSE: Object to form.

22 A. -- good summary.

23 Q. You sometimes rely on meat-analyses,  
24 correct?

25 A. Yes.

1 Q. One of the meta-analyses you cited in  
2 connection with your report was a meta-analysis on  
3 whether there was any long-term effects of NAS.

4 Do you remember that one?

5 A. No. Which one?

6 Q. Why don't you look at footnote 35. You say  
7 Baldacchino. There is a cite on page 12 of your  
8 report.

9 A. Oh, here.

10 Q. You cite it for the proposition: Long-term  
11 studies have shown that toddlers and young school-age  
12 children with prenatal opioid exposure are more likely  
13 to have impairments in cognition as well as poor  
14 psychomotor and behavioral outcomes.

15 Do you see that?

16 A. I do see that. I'm reading it right now.  
17 Yes.

18 Q. And this particular paper is a meta-analysis,  
19 right?

20 A. Yes.

21 Q. Do you have any problems with the conclusions  
22 of the authors in this meta-analysis?

23 A. Which one specifically?

24 Q. Well, they have specific conclusions in their  
25 paper where they concluded that their meta-analysis

1     showed no increased risk of anything, right?

2             A.   I would have to look at that paper directly.

3             Q.   So this is one of two papers that you have  
4     cited.   The other one happens to be footnote 70.

5             Maybe it's just a coincidence.   The Merhar  
6     paper?

7             A.   Merhar.   Yes.

8             Q.   Page 20.   I think you have referenced this  
9     before.   This one was a review of neurodevelopmental  
10    outcomes in infants.   So this is not a meta-analysis.  
11   This is not a prospective study.   This is a  
12   retrospective paper, correct?

13            A.   That is correct.

14            Q.   And is there a difference in your view in  
15   terms of the reliability of a retrospective paper  
16   versus a prospective study?

17            MS. KEARSE:   Object to form.

18            A.   It depends on -- usually, the gold standard  
19   is a prospective, but I think if you have great data  
20   that a retrospective study is -- definitely can give  
21   you information.

22            Q.   Okay.   So there are actually two studies that  
23   you have cited here in this particular citation.   I  
24   think that we know the one above it is the torticollis  
25   paper.

1 A. Uh-huh.

2 Q. You already mentioned this, right?

3 A. Yeah.

4 Q. So you say: Infants with opioid exposures  
5 are more likely than infants with no drug exposures to  
6 be diagnosed with behavioral or emotional disorders,  
7 developmental delay, lower developmental scores,  
8 speech disorder, strabismus, increased incidence of  
9 torticollis and associated plagiocephaly, flat heads,  
10 right, and more likely to be exposed to the  
11 hepatitis C virus.

12 And then you cite both of those papers.

13 Do you see that?

14 A. Yes, that is correct.

15 Q. And the McAllister paper at footnote 69 is  
16 the one with the torticollis and plagiocephaly,  
17 correct?

18 A. Yes.

19 Q. So you're setting the next paper, the Merhar  
20 paper for all of the rest of it, right?

21 A. So that's a combination, and I think some of  
22 that might have been associated with our development.  
23 I might have been incorporating our last paper that I  
24 have added onto our CV.

25 Q. The hep C part?

1           A. No. The one that is published, the  
2   developmental outcomes comparisons with opioid  
3   exposure.

4           Q. So the question is: Are there specific  
5   papers besides the two that we have identified, Merhar  
6   in footnote 70, and Baldacchino in footnote 35, that  
7   you cite for the proposition that there is evidence  
8   suggesting long-term deficits in terms of behavior,  
9   emotion, developmental delay, lower developmental  
10   scores?

11          A. There are multiple other papers. I just  
12   didn't cite all of them.

13          Q. Okay. And the Baldacchino one obviously does  
14   take ultimately multiple studies and puts them through  
15   its meta-analysis, right?

16          A. And the -- that publication -- what page was  
17   that on again?

18          Q. Twelve.

19          A. Twelve? So that meta-analysis was published  
20   in 2014, meaning it went back to studies prior to that  
21   time, where I don't think our numbers were as high.

22                 So I think our more current data, which I  
23   know all took place at our institution, I weighed more  
24   than that meta-analysis.

25          Q. Okay. Can you identify those additional

1 studies you're referencing?

2 A. I think it is in one of PowerPoints I had, if  
3 we have it. There is a list of just a generalizable.  
4 I know there is four that develop -- that talk about  
5 neurodevelopmental outcomes. I -- I talk -- we have a  
6 generalized slide in one of our PowerPoints.

7 (AmerisourceBergen-Wixelblatt-002 was marked  
8 for identification.)

9 Q. So I'm handing you what's been marked as  
10 Exhibit number 2 for the deposition. There is an  
11 additional copy there for plaintiffs' counsel. And  
12 this was provided with your report as Wixelblatt  
13 Materials Considered.

14 Do you see this?

15 A. Yep.

16 Q. Are you familiar with this document and the  
17 way it fits with your report, Exhibit 1?

18 A. So, yeah. That's the second paper that I was  
19 talking about. I may have put some of that  
20 information into that footnote 69 and 70.

21 Q. So let's just make sure it is clear for the  
22 record. So what this says is the materials you  
23 considered are the ones referenced in the report,  
24 which are the -- about 50 papers and citations in the  
25 report, many of them in here twice, which is why the

1 citation number is up.

2 And then there are seven additional citations  
3 as things that you've considered, right? So if you  
4 put together the citations in the report, plus the  
5 seven specific citations here, altogether then these  
6 are the, like I said, roughly 57 total citations or  
7 materials you considered in connection with doing your  
8 report, correct?

9 A. In addition to the other one that we  
10 mentioned earlier about the administrative database.

11 MS. KEARSE: Counsel, I would also say his  
12 resume that has publications that he's published. I  
13 don't know if they're all cited or not, but I think  
14 that was clear on that's his reliance on anything that  
15 he's published as well.

16 Q. Well, are there articles that you published  
17 that aren't referenced in the report or listed here  
18 that are relevant to the issues that we have been  
19 discussing?

20 A. Not on the updated CV. They're all listed.

21 MR. ALEXANDER: We will mark the updated CV  
22 because you refer to it. And frankly, I don't see any  
23 need to mark the old one. I only have one copy of the  
24 updated CV, which plaintiffs' counsel provided  
25 earlier. I'll mark that as Exhibit 3.



1 (AmerisourceBergen-Wexelblatt-003 was marked  
2 for identification.)

3 THE WITNESS: Do you need this, sir?

4 MS. KEARSE: That's the old one?

5 MR. ALEXANDER: That's the new one that you  
6 gave me. You gave me one copy.

7 MS. KEARSE: Okay.

8 MR. ALEXANDER: I assume you have one  
9 yourself?

10 MS. KEARSE: Yeah, I did. So you're making  
11 that an exhibit. I though you said you were going to  
12 use the old.

13 This is mine. I don't need any other copy.

14 Q. So what you were saying, Dr. Wexelblatt, is  
15 that the paper here listed Hall, McCallister,  
16 Wexelblatt, published last year in something called  
17 the Population Health Management?

18 A. So that actually wasn't published in 2018.  
19 It was published in 2019. The abstract was available  
20 online in 2018, and that's why I updated it on the CV  
21 to show when it was in press.

22 Q. And that's called Developmental Disorder --  
23 I'm sorry, Development Disorders and Medical  
24 Complications among Infant with Subclinical  
25 Intrauterine Opioid Exposures?

1 A. That is correct.

2 Q. Okay. So, what does "subclinical" in this  
3 context mean?

4 A. Not needing pharmacologic treatment.

5 Q. Okay. So these are not NAS babies, as you  
6 define them?

7 A. They are babies that have opioid exposure  
8 that are did not need pharmacologic treatment.

9 Q. In your report, you're not opining on the  
10 need to do anything in terms of additional follow-up  
11 specifically with this subset of opioid exposed but  
12 non-NAS babies, correct?

13 A. No. Number 50 talks about closer follow-up  
14 is needed for opioid exposed compared to nonopioid  
15 exposed.

16 Q. Is that the extent of the opinions you intend  
17 to give on this subject?

18 A. Well, more about what we are seeing, that  
19 there are differences between opioid exposed not  
20 needing pharmacologic treatment and those that are  
21 nonopioid exposed.

22 And that is what we referenced multiple times  
23 throughout the day today about when I compared them to  
24 the 15,000 in our PP -- our primary care center,  
25 that's the paper that it has been referring to.

1           Q.   Okay.   So where we were when we got started  
2   on all of this was whether there were papers now in  
3   addition to these three, this 2019 Hall paper, and  
4   then the Merhar paper, and the Baldacchino paper that  
5   you cite as you sit here today for the proposition  
6   that there are long-term complications associated with  
7   either NAS or subclinical uterine opioid exposure?

8           A.   Those are the ones I talk about in this  
9   paper.

10          Q.   Are there others that you can identify that  
11   you think are authoritative or definitive on the  
12   subject?

13          A.   Just the ones that we reference within these  
14   papers I think give a background on each of these  
15   subjects.

16          Q.   Okay.   And are there specific conditions or  
17   findings that you would add to the list in paragraph  
18   49 where you talked about -- and which we already  
19   read -- behavioral or emotional disorders going down  
20   through hepatitis C.

21                Are there other conditions that you would say  
22   are more likely to occur because of in uterine -- in  
23   utero opioid exposure whether it result in NAS or not?

24          A.   I think that's a pretty good list.

25          Q.   And are any of these shown to last after the

1 age of two?

2 A. Yes.

3 Q. Which ones?

4 A. Strabismic can. Hepatitis C can.

5 Behavioral, emotional disorders can. Developmental

6 delay can. Lower developmental scores can. And

7 speech disorders can.

8 Q. Okay. So --

9 A. Mainly the only ones that are not that are  
10 usually treated and addressed are the torticollis and  
11 the plagiocephaly.

12 Q. Okay. And in terms of the behavioral and  
13 emotional disorders, developmental delays, lower  
14 developmental scores, speech disorder, I'll put those  
15 together.

16 Those are not identified as being a specific  
17 physiologic difference, correct?

18 A. Define physiologic difference.

19 Q. Well, for speech disorder, it is not like  
20 there is a problem with the palate or the tongue.

21 These are essentially things measured by  
22 behavior and testing as opposed to an observed  
23 physical difference from the norm?

24 A. There is no physical findings that would  
25 impair speech from that, correct.

1 Q. Okay. And the same thing for anything that  
2 developmental delay, emotional disorders, lower  
3 developmental scores, there is nothing that has been  
4 described like there is a difference in brain  
5 structure or some other anatomic structure that would  
6 explain any of this?

7 A. They're looking at MRIs, formation and brain,  
8 so I don't know if we have that answer, but I know it  
9 is being looked at.

10 Q. And this is where we have the significant  
11 issue we have talking about: The import of or the  
12 potential confounding factors of socioeconomic status  
13 and other things that are potential determinants of  
14 poor outcomes in terms of emotional delays, behavior,  
15 developmental, when somebody is raised by somebody who  
16 is addicted to drugs or is otherwise in one of these  
17 circumstances that may be high trauma and high  
18 difficulty --

19 MS. KEARSE: Object to form.

20 Q. -- correct?

21 A. The thing is most of our patients with NAS  
22 don't fall into that category. The majority are  
23 falling into MAT. So that would maybe take that  
24 out.

25 Q. Are you seeing some difference on any of

1     these things with MAT-treated mothers who give birth  
2     to babies that have these -- well, let me ask it this  
3     way because -- the babies aren't treated. You're  
4     talking about MAT to the mothers during pregnancy?

5             A.    Correct.

6             Q.    Versus illicit drug use during pregnancy?

7             A.    So we are talking about their opioid  
8     exposure.

9             Q.    Are you seeing some difference in terms of  
10    long-terms effects that are nonphysiologic in nature,  
11    depending on whether the mother received MAT during --  
12    during pregnancy or whether she was using illicit  
13    drugs during pregnancy?

14            A.    We are in -- our number of babies at this  
15    time isn't powered enough to figure that out, but we  
16    are looking at that.

17            Q.    Are you looking at that in connection with  
18    any particular research project?

19            A.    It's part of our NAS clinic, which is a  
20    hybrid -- clinical/research clinic.

21            Q.    And are you seeing anything so far that lets  
22    you have a hint as to what the data shows?

23            A.    We are not powered yet, so we wouldn't look  
24    until we had a large enough power to see.

25            Q.    Power and statistical considerations matter

1 to you, right?

2 A. Yes.

3 Q. You're like a clean researcher, you want  
4 statistical significance, you want to only have things  
5 where the original selected end point is met according  
6 to the original statistical criteria?

7 MS. KEARSE: Object to form.

8 A. And that's what I have used for -- reasons to  
9 put papers in here.

10 Q. You're not one of these people who will say  
11 it is not statistically significant but there was some  
12 trend and you're going to rely on that as showing  
13 something as having been proven or demonstrated,  
14 right?

15 MS. KEARSE: Object to form.

16 A. All of these things listed, especially on 49,  
17 had a P value of less than .205.

18 Q. And is that typically what you use in your  
19 studies?

20 A. Yes.

21 Can we take a break?

22 MS. KEARSE: Is it a good time for break yet?

23 MR. ALEXANDER: It's a good time for a break.

24 THE VIDEOGRAPHER: We are now going off  
25 record. The time is 2:56.

1 (There was a brief recess.)

2 THE VIDEOGRAPHER: We are now back on  
3 record. The time is 3:30.

4 Q. Dr. Wexelblatt, we had a nice long break.  
5 You still going strong?

6 A. Yes, sir.

7 Q. Are there any of your opinions so far that  
8 you need to change or supplement in any way?

9 A. Yes, I did find that literature review that I  
10 mentioned in my talk that discusses studies that have  
11 shown infants being exposed to opioids at a higher  
12 risk for. If you would like that list.

13 Q. Sure. Can I see that, please?

14 How was it that you came to find this during  
15 the break?

16 A. We -- I have it on my computer, my docs.

17 Q. Okay. You went to look for it, is that what  
18 you're saying?

19 A. That we have -- yeah, it is on my --

20 Q. You keep saying "we" sometimes and then "me."  
21 So I'm just trying to understand what.

22 Did you find this during the break?

23 A. I found it. Anne has a copy of it from  
24 previously giving it to her.

25 Q. All right. So looking at this, the paper



1     cited, if I understand the citation for Hall,  
2     McAllister is the one we went over, that's your paper  
3     that now is published in 2019, but it is described  
4     here as being 2018 because that's when the abstract  
5     was, correct?

6           A.   That was when it was available online,  
7     correct.

8           Q.   And so we have one of the other papers we  
9     already described, the Merhar paper. And then there  
10    are a couple other older papers.

11          A.   Right.

12          Q.   And then there is one other newer paper that  
13    isn't described in here. Morris and Hall, Wexelblatt,  
14    McAllister abstract PES 2019.

15               What is that?

16          A.   That's one that we mentioned earlier with the  
17    strabismus.

18          Q.   Okay. All right. So in terms of the issues  
19    we were talking about before, neurodevelopmental  
20    delays, executive functioning, memory, attention,  
21    behavioral problems.

22               There is the Merhar paper, which is in the  
23    report, the Hall paper, which we have identified  
24    already, and then some other older papers, Sundelin,  
25    Scovland and Conan and Burke, if I'm saying that name

1 right. Had a couple Js in there somewhere.

2 Does that sound about right?

3 A. If that's what that list says, yes.

4 Q. And so this is from a presentation that you  
5 gave how recently?

6 A. Within the last year. I think this was from  
7 September at the Ohio AAP meeting, which is listed on  
8 my CV as my most second to recent talk.

9 Q. Is this the entire presentation?

10 A. Looks like you had it all along.

11 Q. And does it end with the thing about Abe  
12 Lincoln?

13 A. Yeah.

14 Q. -- saying that the internet is fake and he's  
15 taking a selfie, that's the one?

16 A. That would be the one.

17 Q. Okay. And this is also where you have the,  
18 It takes a village thing that we talked about?

19 A. That's not in that doc, I don't think.

20 Q. Okay. Maybe some other piece.

21 A. That's a OPQC one.

22 I talked over him. I apologize

23 Q. There was at least one other kind of silly  
24 jokish thing in here besides the Abe Lincoln thing,  
25 but we can find it another time.

1 A. Yeah.

2 Q. So that was a talk that you gave called  
3 neonatal abstinence syndrome delivered by you directly  
4 at -- was that given at Cincinnati Children's or some  
5 other venue for the talk?

6 A. That was presented at the Ohio Chapter --  
7 that was presented in Columbus, Ohio.

8 Q. And what was the event?

9 A. That was Ohio Chapter of American Academy of  
10 Pediatrics annual meeting.

11 Q. So the other silly thing I was thinking about  
12 here is you've got an apples to oranges comparison of  
13 LeBron James in a Heat jersey for some reason. You  
14 must not know your venue, or Michael Jordan from a  
15 video game.

16 Do you remember that?

17 A. Yes.

18 Q. Do you stand by everything in this  
19 PowerPoint?

20 A. Yes.

21 Q. Is there an updated version of this or is  
22 this still one that you are giving?

23 A. So I update it before any talk I give, so, to  
24 update data or studies. So, the most recent talk I  
25 gave in March in 2019 at the Tristate Symposium was

1 more focused as it was a 15-minute presentation and  
2 that was more -- those slides are -- it was mostly on  
3 the epidemiology in our region.

4 Q. Okay.

5 A. But from that slide deck. It is just not the  
6 full slide deck.

7 Q. Why don't we walk through then the papers  
8 that we have that we have identified, including up to  
9 the paper that you were on with Hall that published  
10 earlier this year. Okay?

11 A. Okay.

12 Q. So I've marked as Exhibit 4 -- did you say  
13 it's Merhar, or do you pronounce it differently?

14 A. Merhar. But I'll know who you are referring  
15 to if you say it that way.

16 Q. So here is a copy for you marked as  
17 Exhibit 4. This is, for the record, the Merhar paper,  
18 from Journal of Perinatology 2018, called Retrospect  
19 review of neurodevelopmental outcomes in infants  
20 treated for neonatal abstinence syndrome. And there's  
21 a copy for plaintiffs' counsel as well.

22 (AmerisourceBergen-Wexelblatt-004 was marked  
23 for identification.)

24 MR. ALEXANDER: Actually, I'm going to mark  
25 four of them. That will just speed it up. And we

1 will go from there.

2 I have for you your paper, Exhibit 5. This  
3 is the Hall paper, Developmental Disorders and Medical  
4 Complications Among Infants with Subclinical  
5 Intrauterine Opioid Exposures, published earlier this  
6 year in Population Health Management.

7 That's Exhibit 5, and there is a copy for  
8 plaintiffs' counsel as well.

9 (AmerisourceBergen-Wexelblatt-005 marked was  
10 for identification.)

11 MR. ALEXANDER: I have the Baldacchino paper  
12 that we mentioned as Exhibit 6. That is  
13 Neurobehavioral consequences of chronic intrauterine  
14 opioid exposure in infants and preschool children: a  
15 systematic review and meta-analysis.

16 Published in BMC Psychiatry in 2014, and a  
17 copy for plaintiffs' counsel.

18 I also have a copy of the ACOG Committee  
19 Opinion Number 711 from ACOG and the American Society  
20 of Addiction Medicine. And that is from August of  
21 2017.

22 A copy of that for plaintiffs' counsel as  
23 well.

24 (AmerisourceBergen-Wexelblatt-006 was marked  
25 for identification.)

1 (AmerisourceBergen-Wexelblatt-007 was marked  
2 for identification.)

3 Q. What I would like to do -- we will start in  
4 maybe chronological order just so we understand  
5 because I think you have talked about the evolution of  
6 the literature in this area.

7 So the first one chronologically out of  
8 these, ignoring all of the references and stuff, is  
9 the Baldacchino paper.

10 Do you see that?

11 A. Yes.

12 Q. So that's Exhibit 6, correct?

13 A. This one doesn't have a number on it.

14 Q. Then you handed the one with the sticker to  
15 the plaintiffs' counsel, and you always keep the one  
16 with the stickers.

17 MS. KEARSE: And I just messed all of these  
18 up. All right. So this is --

19 Did I not give you a sticker copy?

20 THE WITNESS: Yep. It was in -- yeah.

21 MS. KEARSE: So this is 6?

22 MR. ALEXANDER: This is 6.

23 MS. KEARSE: I don't want to slow the record  
24 down, but can you just give me the numbers of what is  
25 corresponding to what?

1 MR. ALEXANDER: Five is Merhar. Six is  
2 Baldacchino.

3 THE WITNESS: No. Four is Merhar.  
4 Retrospective review is Number 4.

5 Developmental disorders is Number 5.

6 ACOG is 7.

7 Q. Okay. Let's start with the first in time,  
8 Number 6, the Baldacchino paper, which we have talked  
9 about a little bit, correct?

10 A. Yes.

11 Q. Okay. So, we have talked about what a  
12 meta-analysis is, correct?

13 A. Correct.

14 Q. And you obviously didn't just read the  
15 abstract; you read the whole paper, correct?

16 A. Awhile ago on this paper, but yes.

17 Q. When you write papers, do you ever have to  
18 write up an abstract section to follow a specific  
19 format to summarize what happens in the paper?

20 A. Yes. Each journal has different word  
21 limitations and styles that they want. So, majority,  
22 the average I would say is 250 words is allowed for an  
23 abstract.

24 Q. And this paper is authors out of Scotland,  
25 correct?

1           A. It does say that they are out of University  
2 of Dundee.

3           Q. And do you know what the history is of trends  
4 in terms of opioid exposure during pregnancy and high  
5 opioid use in Scotland?

6           A. No.

7           Q. Do you know if that is one of places where  
8 there has been a lot of research because they have  
9 pretty high historic narcotic and opioid use among  
10 European countries?

11           MS. KEARSE: Object to form.

12           A. I'm not aware of that.

13           Q. Okay. So under the Results section -- just  
14 start with the abstract for completeness.

15           The second -- the third sentence says: This  
16 meta-analysis showed no significant impairments at a  
17 nonconservative significance level of P less than 0.05  
18 for cognitive psychomotor or observed behavioral  
19 outcomes for chronic intrauterine exposed infants and  
20 preschool children compared to nonexposed infants and  
21 children.

22           Do you see that?

23           A. I do see that.

24           Q. And just so we are on the same page as it  
25 relates to your presentation, cognitive, psychomotor,



1 and observed behavioral outcomes, those do overlap  
2 with the topics that you identify, right?

3 A. Correct.

4 Q. I mean, you don't have a psychomotor  
5 category, do you?

6 A. In which paper are you referring to?

7 Q. I was saying as you've broken it out in the  
8 one page from your presentation that you pulled out  
9 earlier.

10 A. No, we don't break it out that way.

11 Q. Okay. But you have cognitive and behavioral,  
12 correct?

13 A. In my --

14 Q. Executive functioning --

15 A. Yes.

16 Q. So we're talking about the same sort of  
17 measures, correct?

18 A. Correct.

19 Q. And you said P -- a P value of .05 is what  
20 you typically use in your studies, correct?

21 A. Correct.

22 Q. Which is the standard and what you think is  
23 appropriate for doing research, right?

24 A. I do agree with that.

25 Q. So if you go to the body of paper, they talk

1 about their process for doing the meta-analysis, and  
2 then they give their results with -- with regard to  
3 each of the things that they looked at starting on  
4 page 6 of 12.

5 Do you see that?

6 A. Page 6 of 12, the Results section?

7 Q. You see -- yeah, the top right corner, it  
8 says page blank of 12.

9 Do you see that? The top right corner of  
10 each page --

11 A. Yes.

12 Q. -- it says page 6 of 12 or 7 of 12.

13 A. Yes.

14 Q. And so as you go through these, of  
15 neurobehavioral function, and then the examination of  
16 opioid exposed infants compared to nonopioid exposed  
17 infants, with regard to each of these things they say,  
18 -- this is their scientific language, the null  
19 encompasses was not different, or it says the --  
20 basically the language they use is that the null  
21 hypothesis could not be rejected.

22 Do you see that language?

23 A. Can you just -- where are you? I'm sorry. I  
24 just --

25 Q. It is under -- it's a repeating phrase that's

1     used in each of the sections starting on the right  
2     column of page 7 of 12. And it doesn't really matter.  
3     I'm asking you what -- the phrase, "the null  
4     hypothesis could not be rejected" is basically, we  
5     couldn't establish that there was a difference?

6           A. Correct. So that trend crosses the zero  
7     number, meaning you -- it doesn't meet the  
8     statistical, it is more of a trend in this -- the  
9     papers.

10           Q. And so then if you go to the Discussion  
11     section on page 8 of 12, they have a direct statement  
12     for all of these: Our findings -- so this is under  
13     Discussion, Key findings -- and it looks like it is  
14     about the third sentence.

15           It says: Our findings indicate no  
16     significant impairments in cognitive, psychomotor or  
17     observed behavioral outcomes for chronic intrauterine  
18     exposed infants and preschool children.

19           Do you see that?

20           A. I do see that.

21           Q. And you think that's a fair reading of their  
22     research, correct?

23           A. Right. Well, in the last statement that  
24     continues that, "...although in all domains there is  
25     trend to poor outcomes..."

1 MS. KEARSE: Counsel, can I -- I know that  
2 you made this article an exhibit, but I don't think  
3 this is the final article of this paper. There is a  
4 corrected publication of this.

5 MR. ALEXANDER: This is the citation that he  
6 has in his thing, and if it's an objection, then it's  
7 an objection.

8 MS. KEARSE: Okay. Well, we can --

9 MR. ALEXANDER: This is what I believe is  
10 exactly what he cited as is.

11 MS. KEARSE: Maybe go off the record for a  
12 second.

13 Q. So I'm not sure I got an answer to my  
14 question.

15 MR. ALEXANDER: Could we have the answer read  
16 back from the last pending question?

17 MS. KEARSE: Well, I just don't want to  
18 confuse the witness if this is not the specific  
19 article in there, too, because there is a corrected  
20 version of this article. So --

21 MR. ALEXANDER: I mean, I'm sure you're  
22 allowed to object to form, and that's about it, but go  
23 ahead.

24 MS. KEARSE: Well, if this is not the updated  
25 article, I'm here to amend it --

1 THE WITNESS: Yeah, and --

2 MS. KEARSE: -- and to be asking about that.

3 MR. ALEXANDER: Yeah. So, I'm sorry.

4 Did we have an answer to the last question,  
5 ma'am?

6 THE WITNESS: So I was stating that  
7 "...although in all domains there was a poor  
8 trend....," so meaning that the P value wasn't  
9 significant, but it was above zero --

10 Q. I'm sorry --

11 A. -- is what their discussion is stating.

12 Q. Do you think the statement, "Our findings  
13 indicate no significant impairments..." for each of  
14 these things is a fair statement of what they actually  
15 found according to the scientific standards that they  
16 used and you think should be used?

17 A. And as long as you add in the last statement  
18 that "there is trends to poor outcomes....," yes.

19 Q. Right. As we said earlier, you, as a  
20 researcher and a rigorous scientific mind, don't go  
21 off of mere trends, you require something to be  
22 statistically significant before you would rely on it  
23 as establishing anything, correct?

24 A. Right. So there is a trend, then we would  
25 investigate it further.

1 Q. Okay. Got it. That's why we are going  
2 through these chronologically.

3 A. Yes.

4 Q. If you go to the page 10 of 12 that says  
5 Clinical Relevance.

6 It says: This meta-analysis helps in  
7 supporting certain clinical observations in this  
8 population. The observed, if any, neurobehavioral  
9 outcomes in infants and preschool children prenatally  
10 exposed to opioids are very often attributed to  
11 substance exposure.

12 Do you see that?

13 A. I do see that.

14 Q. However it is important to examine the  
15 contribution of other influences on a child's  
16 development.

17 Do you agree with that so far?

18 A. I agree that's what is written, yes.

19 Q. Do you agree with those two statements so  
20 far, that often there will be maybe a facile  
21 attribution to substance exposure, but it is important  
22 to examine the contribution of other influences on a  
23 child's development?

24 A. Yeah. That time when this was written in  
25 2014, I think that was a very good statement.

1           Q. It continues: Ongoing maternal depressive  
2 illness is correlated with poor cognitive and motor  
3 development and increase in teacher and parent rated  
4 behavior problems in preschool children. Poverty and  
5 low socioeconomic status is inversely related to  
6 children's developmental performance.

7           You agree with both of those statements,  
8 right?

9           A. I'm -- and I don't know about this -- this  
10 paper, I don't know if I correctly cited.

11           So I think this is the first time I am seeing  
12 and I may have -- so I don't know if I put the correct  
13 statement -- the title in this paper, but this is a  
14 paper that I'm reviewing now.

15           MS. KEARSE: Can we go off record one second?  
16 I think it is --

17           THE VIDEOGRAPHER: We are not off record. Do  
18 you agree to go off record?

19           MR. ALEXANDER: No.

20           MS. KEARSE: Okay.

21           MR. ALEXANDER: I want him to answer the  
22 questions I have.

23           MS. KEARSE: Okay.

24           MR. ALEXANDER: Without coaching. And if he  
25 can --

1 MS. KEARSE: Well, I'm not coaching. That's  
2 why I was going to go off record, so --

3 MR. ALEXANDER: Well, that's what's  
4 happening, so why don't we just go with question and  
5 answer. If you need to clean it up, you can ask your  
6 own questions and then we get to ask ours after you  
7 ask yours. That's how it works.

8 I don't want to have my time taken up with  
9 this.

10 MS. KEARSE: Okay. Well, we'll correct it.

11 Q. Dr. Wexelblatt --

12 A. Yes, sir.

13 Q. Okay. So, if you continue on in the same  
14 paragraph, it says: Factors that become -- actually,  
15 I'm sorry.

16 The last two sentences I asked you about, did  
17 you agree with those, the one that starts with,  
18 Ongoing maternal depressive illness and then continues  
19 about poverty and low socioeconomic status?

20 Do you agree with those two statements?

21 MS. KEARSE: I'm going to have a running  
22 objection. Until he has the article in front of him.  
23 It's cited correctly, but it's not the actual article  
24 that is -- that -- that there's an errata there,  
25 correction of the --



1 MR. ALEXANDER: You can have a running  
2 objection. That is an improper objection according to  
3 the Court's rules.

4 MS. KEARSE: Well, I'm just saying it's --  
5 you indicated it -- it was cited and you looked it up  
6 this way. If you look it up in the publication, it's  
7 not this article.

8 MR. ALEXANDER: Again, coaching, improper  
9 objection. Let's -- you can have a running objection,  
10 so you don't need to keep coaching. You can have him  
11 just --

12 MS. KEARSE: I'm not coaching.

13 MR. ALEXANDER: -- answer the questions.

14 MS. KEARSE: It's actually a fact of the  
15 article. You said you looked up from the citation,  
16 and if you looked it up from the citation, I don't  
17 think you would have pulled up this article.

18 Q. Dr. Wexelblatt --

19 MS. KEARSE: I would just say, this article,  
20 there is a correction to it. We will go over that on  
21 redirect.

22

23 BY MR. ALEXANDER:

24 Q. Dr. Wexelblatt, I'm not I got an answer to my  
25 question.

1           The sentences in the Clinical Relevance  
2    section of this paper that say: Ongoing maternal  
3    depressive illness is correlated with poor cognitive  
4    and motor development and increase in teacher and  
5    parent rated behavior problems in preschool children;  
6    and: Poverty and low socioeconomic status is  
7    inversely related to children's developmental  
8    performance.

9           Do you agree with both of those?

10          A. I would agree with the second one, and the  
11    first one I do not know.

12          Q. Okay. This continues, if you go down a  
13    little bit: Factors that became significantly  
14    associated with neurobehavioral outcomes included low  
15    socioeconomic status, low maternal IQ, poor quality of  
16    the home environment, and children's lead exposure.  
17    Overall it is increasingly becoming evident that the  
18    risk factors that can pre poor neurobehavioral  
19    outcomes is not the drug-fuelled lifestyle or actual  
20    substance exposure during pregnancy, but the presence  
21    of multiple interrelated and weighted variables  
22    cumulatively influencing neurobehavioral outcomes.

23          Do you see where I read?

24          A. So is that -- I did see that and it is  
25    referring to studies that happened around 2000 and

1     2001. So, I think going back to that time period,  
2     that is probably is correct.

3             Q. Okay. So, my question is: Do you agree with  
4     those statements?

5             A. No. Because I think that we have evolving  
6     information to go against that.

7             Q. Okay. As of 2014, was it the consensus that  
8     it was the presence of multiple interrelated and  
9     weighted variables that have influenced  
10    neurobehavioral outcomes in children who had in utero  
11    exposure to opioids or opiates?

12            A. I would have to change that date to 2002 is  
13    the average, looks like, paper written during this  
14    time period. So you would have to go back to then,  
15    not 2014 when it was published.

16                    You would have to look at when the  
17    meta-analysis looked at the papers. And so those  
18    papers are 2008, 1998, 2001, 2001, 2001.

19            Q. Okay. So then it continues: The risk  
20    factors were: maternal mental health, maternal  
21    attitudes towards parenting and maternal-child parent  
22    interaction, maternal education, parental occupation,  
23    minority status, stressful life events and family size  
24    with not one risk factor contributing exclusively to  
25    one cognitive or neurobehavioral outcome.

1 Do you see that?

2 A. Yes, I see that.

3 Q. Did you disagree with that one, too?

4 A. I think that was probably true in 2002. I  
5 think we have had a lot more evolution in the  
6 literature to change that mind-set.

7 Q. So in terms of your ongoing research -- we  
8 have talked about this.

9 You said that you track socioeconomic status,  
10 and you're unable to keep tracking maternal education  
11 level, correct?

12 A. We are not unable to. We have decided not to  
13 because of the amount of time that it took to get that  
14 information. It wasn't easily pullable from the EHR,  
15 that we decided to focus on things that we thought  
16 were more important.

17 Q. Okay. So are you tracking maternal  
18 depressive illness?

19 A. That is part of the problem set.

20 Q. So you will be going forward tracking that?

21 A. We always have looked at that.

22 Q. How about low maternal IQ, are you tracking  
23 that?

24 A. No. But that is a -- listed on the mother's  
25 problem list, so that is tracked. If she does have a

1 significantly lower IQ, that would fall outside of the  
2 standard deviations and make her have mental  
3 retardation.

4 Q. What about low -- I'm sorry, poor quality of  
5 the home environment?

6 A. That is not looked at.

7 Q. Child lead exposure?

8 A. Luckily, we are not seeing that much  
9 anymore.

10 Q. Okay. What about maternal mental health,  
11 more broadly than just depression, are you tracking  
12 that?

13 A. We are addressing it in our MOMS Project,  
14 yeah. That's one of the main focuses is maternal  
15 mental health.

16 Q. I'm saying for your purposes of your  
17 research.

18 A. As part of our ongoing NAS clinic, yeah,  
19 that's part -- one of -- we have the mom's problem  
20 list in there.

21 Q. The papers you published already don't track  
22 that as a factor to correct for?

23 A. Not everything we -- if there is stuff that  
24 we are finding that doesn't have an effect to our  
25 opinion, we don't list everything that may not be in

1     there.

2           Q.   So if you try a correction, it wouldn't  
3     change things; that's the whole point, right?

4           A.   Correct.

5           Q.   Okay.   So in your published papers on this  
6     issue, you haven't corrected for maternal mental  
7     health, maternal attitudes towards parenting and  
8     maternal child parent interaction, correct?

9           A.   Correct.

10          Q.   And you haven't accounted for maternal  
11     education --

12          A.   We have --

13          Q.   -- after that first paper?

14          A.   Yes, we have not continued that.

15          Q.   You haven't accounted for parental  
16     occupation?

17          A.   Correct.

18          Q.   You said you accounted for race, that you  
19     said you had some higher findings in Caucasians, so I  
20     guess that means you have accounted for minority  
21     status?

22          A.   Yes.

23          Q.   Stressful life events and family size, do you  
24     account for either of those?

25          A.   We didn't find any change when we looked at

1 family size for our first one, so we stopped tracking  
2 it as it didn't have any risk factors.

3 Q. Okay. Why don't we go to the next one in  
4 time. The ACOG committee opinion, which should be  
5 Exhibit 7.

6 And we talked about this earlier, in general,  
7 that you identify this and you talked about various  
8 recommendations this makes regarding treatment and  
9 diagnosis and screening with regard to opioid use --  
10 opioid use disorder in pregnancy, correct?

11 A. Correct.

12 Q. And this is cited in your report in multiple  
13 places, right?

14 A. It is.

15 Q. I'm going to jump to the relevant part for  
16 our current discussion and then we may go back to a  
17 little bit more.

18 This does have a discussion as of August of  
19 2017 based upon the consensus work of a committee of  
20 experts from the American College of Obstetricians and  
21 Gynecologists, and the American Society of Addiction  
22 Medicine. It has a discussion about this issue of  
23 long-term infant outcomes, correct?

24 A. There is a section on that on page 10.

25 Q. So on page 10, there is a section that talks

1 about neonatal abstinence syndrome, correct?

2 A. Yes.

3 Q. And that's part of what you've actually cited  
4 in your report, correct?

5 A. I -- this is most of the information -- that  
6 is -- a lot of information I think is -- I take that  
7 back.

8 This stuff in -- under Neonatal Abstinence  
9 Syndrome, I would have to review right now to see what  
10 made it into the report or not. As you know, there is  
11 lot of papers that went into this.

12 Q. Yeah. So I mean, like for instance, I can --  
13 I can help you. If you go down about three-quarters  
14 of way, there are things that I think are very  
15 directly stated in your report as adopting the same  
16 kind of recommendation. I'm not saying you -- you  
17 copied them or anything, but it is the same.

18 Each nursery should develop an evidence-based  
19 written policy to assess and treat an infant with  
20 neonatal abstinence syndrome and women should be  
21 informed of key components of these policies.

22 That's very much like one of the proposals  
23 we went over, right?

24 A. Yeah. I think that is taken from our paper  
25 in Pediatrics.



1 Q. And it says: Families should be encouraged  
2 to visit and care for their infants and women should  
3 be supported in their effort to breastfeed their  
4 infants, if appropriate?

5 A. That is also correct.

6 Q. Okay. Are you a member of either of those  
7 organizations, ACOG or ASAM?

8 A. No.

9 Q. Were you somebody who participated in this  
10 ACOG Committee Opinion?

11 A. No, but I think our papers are cite in it.

12 Q. They are. A couple of them.

13 A. Yep.

14 Q. So the Long-Term Infant Outcomes section is  
15 right after the section of Neonatal Abstinence  
16 Syndrome, correct?

17 A. That is correct.

18 Q. And it says: Long-term outcomes of infants  
19 with in utero opioid exposure have been evaluated in  
20 several observational studies.

21 A major challenge in assessing these outcomes  
22 is isolating the effects of opioid agonists from other  
23 confounding factors such as use of other substances  
24 (tobacco, alcohol, nonmedical drugs) and exposure to  
25 environmental and other medical risk factors, e.g.,

1 low socioeconomic status, poor prenatal care.

2 Do you see that so far?

3 A. Correct.

4 Q. Do you agree with that so far?

5 A. I do.

6 Q. Do you agree that that is a challenge of  
7 doing research like this?

8 A. It is a challenge.

9 Q. For the most part, studies have been found --  
10 I'm sorry. I'll start over again:

11 For the most part, studies have not found  
12 significant differences in cognitive development  
13 between children up to five years of age exposed to  
14 methadone in utero and control groups matched for age,  
15 race and socioeconomic status, although scores were  
16 often lower in both groups compared with population  
17 data.

18 Do you see that?

19 A. I do see that, and know that that was cited  
20 from the one paper, yes.

21 Q. Yeah, the citation 88 is to the Kaltenbach  
22 paper --

23 A. Uh-huh.

24 Q. -- from 1984.

25 A. That is correct.

1           Q.   Okay.  I have that paper here if there is a  
2   need to look at it, but I don't think there is for  
3   these questions.

4           It says --

5           MS. KEARSE:  We offered it.  If he wants to  
6   look at it.

7           Q.  -- Preventative interventions that focus on  
8   supporting the woman and other caregivers in the early  
9   and ongoing parenting years, enriching the early  
10   experiences of children, improving the quality of the  
11   home environment are likely to be beneficial.

12          Do you see that?

13          A.  I do.

14          Q.  And for the record, that's also based on a  
15   really old paper.  That's one from the 1980s.  Okay.

16          So do you agree that this summary of what the  
17   literature showed about long-term infant outcomes with  
18   neonatal abstinence syndrome was correct as of August  
19   of 2017?

20          A.  I think that shows that there was a lack  
21   of -- that the best paper they could come up with was  
22   from the late '90s, showed that there was a huge need  
23   for research, is the way I read that section.

24          Q.  Okay.  So was this a correct statement of  
25   what the literature showed as of August of 2017?

1           A. So that's when it was published, so I --  
2     knowing now a committee member -- opinions meet from  
3     the AAP standpoint, these are usually two years to  
4     develop. So once again, we are going back to 2015  
5     when they were writing this information up.

6           So, yeah, I think at that time we didn't have  
7     an evolving understanding of what the long-term  
8     outcomes are.

9           Q. If you go to the references, I know it  
10    doesn't say exactly when this was all done --

11          A. Uh-huh.

12          Q. -- but if you go to the first two references,  
13    you see that it shows that these were actually  
14    retrieved in March of 2017.

15          Do you see that?

16          A. For that. I was talking about the long-term  
17    outcomes section.

18          Q. I understand. I'm talking about when the  
19    paper was prepared.

20          A. Uh-huh.

21          Q. The first two citations retrieved in 2017.  
22    Next one is an article that only came out in 2016.  
23    The one after that and the one after that, both  
24    retrieved in March of 2017.

25          Do you see that?

1           A. So I don't know what they immediate mean by  
2 "retrieved." I would have to see when they were  
3 actually published, and I don't even know if that was  
4 -- because if you look at number two, it is actually  
5 talking about a 2011 study, it looks like.

6           Q. It's a 2013, that's what it says, actually.

7           A. Number 2 says "Drug Abuse Warning Network"  
8 2013 -- 2011.

9           Q. The publication from SAM says 2013.

10          A. So "retrieve" must be when they downloaded  
11 it, is what I'm reading that.

12          Q. Okay. So if you go on, there are other  
13 studies or papers that weren't published until 2016 or  
14 later --

15          A. Looks like '16.

16          Q. -- that are cited --

17          A. Correct. So that would -- like I said, it  
18 takes it a full year to get these protocols,  
19 correct.

20          Q. Okay. All right. So was this a correct  
21 statement of what the literature showed about  
22 long-term effects, the possibility of long-term  
23 effects in NAS infants as of roughly mid-2016 to  
24 mid-2017?

25               MS. KEARSE: Object to form.

1           A. Once again, I would look at their -- when  
2   they section -- when they looked at all of their  
3   references from that section, the most up-to-date one  
4   was 2013.

5           So, I was -- I do think that this -- it was  
6   focused on the obstetrics side because this is ACOG.  
7   So I don't know where they were getting their  
8   information on neonatal abstinence syndrome or  
9   long-term outcomes besides literature review, which  
10   shows that they were looking at certain papers.

11          Q. Okay. Why don't we go backwards for a little  
12   bit in this paper, because this is something that you  
13   have cited a couple of times.

14          Can you go then to the page 3, which is Role  
15   of the Obstetrician-Gynecologist and Other Obstetric  
16   Care Providers.

17          The last language on page 3, says: Finally,  
18   obstetric care providers have an ethical  
19   responsibility to their pregnant and parenting  
20   patients with substance use disorder to discourage the  
21   separation of parents from their children solely based  
22   on substance use disorder, either suspected or  
23   confirmed.

24          Do you see that?

25          A. I do.

1           Q. Is this issue any part of your proposal, the  
2     issue of whether family separation should be  
3     encouraged or discouraged and what effect it has on  
4     the outcomes for the children?

5           A. So it would depend on each individual person.  
6     So if you just have a substance use disorder and  
7     you're in treatment, well, then, of course, that  
8     should not be a reason to separate the infant from  
9     their mother.

10          Q. That wasn't my question. I said is your plan  
11     addressing at all the issue of how and when children  
12     are separated from parents with a substance abuse  
13     diagnosis, whether they're in treatment or not?

14          A. That would go under social services. That  
15     would be their expertise. So if we could expand our  
16     social services abilities to then determine is this a  
17     safe place for the infant, then, yes.

18          Q. Okay. So do you have specific  
19     recommendations about this?

20          A. So I think that would go back to our --  
21     increasing our social services and our wraparound  
22     services to the mom at the time of discharge to make  
23     sure that she is getting the treatment she needs and  
24     that she has all of the ability to take care of her  
25     child.

1           That would include being in a place in her  
2   recovery, if she does have substance abuse, where she  
3   is able to take care of a baby.

4           Q.   Is there any indication that in some  
5   situations children do better after removal?

6           A.   Define -- depends on what you mean "better."

7           Q.   By the sorts of neurobehavioral outcomes that  
8   we have been talking about.

9           A.   So that's going to come up in this next paper  
10   that you're going to refer to. We did show that  
11   children who live with foster/adoptive families had  
12   higher cognitive scores compared to those who were  
13   with biological relatives.

14          Q.   Right. Doesn't that tell you that sometimes  
15   keeping a child with the biologic mother if she is  
16   having issues with continuing drug use and drug abuse  
17   can have a negative impact on the child?

18          MS. KEARSE: Object.

19          A.   That's why I think you need to address it  
20   individually and not based on a diagnosis.

21          Q.   And so is any portion of your proposal  
22   addressing anything about the standards that are used  
23   for when a child would be kept with the mother versus  
24   pushed towards foster care or adoption?

25          A.   That's where our social services experts



1 would then determine based on their ability to  
2 determine if this is a safe place for a child to go  
3 would come into play.

4 So we would make the referral to the social  
5 service and then let them decide with their abilities  
6 to -- they have access to stuff that we don't have of  
7 -- are there children in foster care, are there --  
8 evidence of abuse that we are not -- have from our  
9 end. So that is where our social services can work  
10 with the counties to know if this is a safe a place  
11 for a baby or not.

12 Q. So you defer to the experts in that field  
13 about whether changes to how things are done in  
14 Cuyahoga and Summit County would be beneficial?

15 A. The disposition is really -- the experts are  
16 the social services to make that determination.

17 Q. So you defer to them on whether there should  
18 be changes to how their policy is that -- in terms of  
19 their criteria for when they recommend placement or  
20 keeping a child with the mother?

21 A. I --

22 MS. KEARSE: Object to form.

23 A. No. I think their current policy is -- is  
24 what we are doing. That's what we are doing now.

25 Q. I'm sorry. You said you don't know what the

1 policy is in Cuyahoga or Summit County on children's  
2 services at all, right?

3 MS. KEARSE: Object to form.

4 A. I work in five counties in this region, and  
5 they all basically have a process what they follow.  
6 So I can't imagine that of our five counties in our  
7 outreach here would be anything much different  
8 because they're a couple hundred miles north.

9 Q. Have you ever read any policies or any  
10 documents at all from Children Family Services for  
11 Cuyahoga County or any equivalent entity for Summit  
12 County?

13 A. No.

14 Q. Okay. If you go to the next section, Effects  
15 of Opioid Use on Pregnancy and Pregnancy Outcomes.

16 It says: The safety of opioids during early  
17 pregnancy has been evaluated in a number of  
18 observational studies. Earlier reports have not shown  
19 an increase in risks of birth defects after prenatal  
20 exposure to oxycodone, propoxyphene and meperidine.

21 Do you see that?

22 A. Yes.

23 Q. And do you agree with that?

24 A. I would have to look at those studies, but I  
25 assume that they did their due diligence and that's

1     what those two studies referred to in 1981.

2           Q.   As it continues, it says:  The observed birth  
3     defects -- from some other studies, observational  
4     studies about possible like neuro tube defects --  
5     remained rare and represent a minute increase in  
6     absolute risk.

7           Do you see that?

8           A.   No, I don't.  Where did you jump down to?

9           Q.   Right in the middle of the paragraph.

10          A.   Oh, okay.

11          Q.   It says:  However, methodologic problems with  
12     these studies exist with potential for recall, bias  
13     and confounding.

14          Do you see that?

15          A.   Uh-huh.

16          Q.   So just to clarify.  What is recall, bias and  
17     confounding?  How does it play into a -- an  
18     observational retrospective study?

19          A.   So those are going on self-report.

20          Q.   That's a problem with relying on self-report  
21     particularly about a history of drug use, right?

22          A.   And I would think -- the way I would read  
23     that is, have you had a child with a neuro tube  
24     defect?

25          Q.   And then they say --

1           A.    I --

2           Q.    -- what they do is, they go backwards and  
3   say, what did you take when you were pregnant?

4           A.    Correct.  I assume that's how that study was  
5   done.

6           Q.    All right.  So the statement:  The observed  
7   birth defects remain rare and represent a minute  
8   increase in absolute risk, do you agree with that as a  
9   statement about birth defects with all prescription  
10   opioids?

11          A.    I think that we have shown that there are  
12   some outcomes that we are finding that have not been  
13   able to be looked at in a way that these papers looked  
14   at them.

15                So, I think at this time, based on those  
16   studies, that is correct, but I think this is an  
17   evolving field that we are learning more stuff about  
18   as we continue to follow patients with NAS.

19          Q.    So if you go to the next section, Screening  
20   for Opioid Use and Opioid Use Disorder in Pregnancy,  
21   there's a discussion about ways that you can screen  
22   and then some stuff about ways that you can test.

23                Do you see that?

24          A.    Yes.

25          Q.    If we go to the second paragraph, it says:

1 Urine drug testing has also been used to detect and  
2 confirm suspected substance use but should be  
3 performed only with the patient's consent and in  
4 compliance with state laws.

5 You alluded to that earlier, correct?

6 A. We did talk about that.

7 Q. Okay. Continues on down. It says: Routine  
8 urine drug screening is controversial for several  
9 reasons. And it gives some of those.

10 And then it continues on, it says: Some  
11 centers have implemented universal urine toxicology  
12 screening for pregnant patients with one study finding  
13 improved rates of detection of maternal substance use  
14 compared with standard methods.

15 Do you see that?

16 A. I do.

17 Q. And do you know what study they're citing?

18 A. That is a Wexelblatt study.

19 Q. It sure is. And is that right, that you had  
20 a universal urine toxicology screening for pregnant  
21 patients?

22 A. It is actually urine toxicology testing for  
23 patients. Screening is different.

24 Q. I'm -- I'm quoting their words. I'm not --

25 A. I know. That's -- they were wrong.

1           Q.   So what did it mean that you had improved  
2   rates of detection of maternal substance use compared  
3   to the standard methods when you had universal testing  
4   of urine?

5           A.   So, we -- universal screening is what the  
6   recommendations are, meaning that you have a question  
7   list or a checklist to determine if you do a test.

8                So what we did is we did -- tested every mom  
9   that showed up, irrelevant of what she had on her  
10   check box or what she said she did on her  
11   questionnaire, her screen.

12               And what we found is -- we looked at every  
13   positive toxicology test and went back and looked at  
14   their moms, and said if she took the screen, would she  
15   have been picked up.

16               And what we found out when we looked at the  
17   opioid positive test, that only -- that 20 percent of  
18   the babies that we identified from moms being  
19   positive, they actually had a negative screen.

20               So we showed that the screen is not as useful  
21   as a test.   A screen is not as useful as a test.

22           Q.   But it says it was universal urine  
23   toxicology, and it says screening, but you say  
24   testing.

25               Does that mean that this was only when they

1 gave consent or was it universal meaning everyone who  
2 showed up?

3 A. We obtained consent on everybody in the  
4 study.

5 Q. It continues talking about your study:  
6 However, the study did not use validated verbal  
7 screening tools in the comparison group, which limits  
8 the usefulness of these results.

9 Do you agree with that?

10 A. Yes.

11 Q. Is that a disclosed weakness of your paper?

12 MS. KEARSE: Object to form.

13 A. No. Because it was our standard of care in  
14 our region, the screen that we utilized.

15 So to get a validated test which they mention  
16 here as the 4Ps, the CRAFFT questionnaire or the NIDA  
17 screen, those are really the only three validated  
18 screens available.

19 Our region had a universal screen that we  
20 used as our standard of care. So that is what we  
21 compared it to. So just because a test has been  
22 validated, I agree there are certain one that are  
23 fantastic, but our thought was -- we thought our  
24 screen was more vigorous than asking a mom four  
25 questions.

1 Q. Does the term mean anything to you when you  
2 talk about a validated screen versus just one you  
3 could use, a comprehensive screen or a more thorough  
4 screen?

5 A. I think validated, when it comes to screens,  
6 just means that you had a research project involved in  
7 determining the validity of the screen.

8 Ours was a standard of care, which means it  
9 is what all of our hospitals in our region did. So to  
10 validate it, we would have had to compare it to  
11 another screen or a different validated screen, but we  
12 thought our risk-based screen was better than just  
13 asking four questions.

14 Q. Why don't we go to the Merhar paper, which is  
15 Exhibit 4.

16 And you've talked about this and cited this  
17 in your report, correct?

18 A. Yes.

19 Q. So, this is a Retrospective review of  
20 neurodevelopmental outcomes in infants treated for  
21 neonatal abstinence syndrome.

22 In terms of the study design, what is it to  
23 do a retrospective cohort study?

24 A. That means we went backwards in time. We  
25 picked a date and said we are going to go back and



1 look at people in the cohort. And our cohort, we  
2 defined as infant that needed pharmacologic treatment  
3 for neonatal abstinence syndrome.

4 Q. You say "we." You're not on this paper, but  
5 it was at your hospital?

6 A. Correct. And it is at our follow-up  
7 clinic.

8 Q. And were you personally involved in designing  
9 or carrying out this paper?

10 A. No, but I did review it for them.

11 Q. So this involves 87 infants, correct?

12 A. Yes.

13 Q. So compared to like the total number of  
14 infants involved in the meta-analysis by Baldacchino,  
15 it's must smaller, correct?

16 A. Correct.

17 Q. And this wouldn't have met the entry criteria  
18 for Baldacchino because it was retrospective cohort  
19 study, correct?

20 A. If that was what their cutoff was for their  
21 prospective -- their meta-analysis, most of the time,  
22 yes.

23 Q. I mean -- and I'm not critical of this paper.  
24 It is whatever it is.

25 A. Yeah.

1 Q. This is not a high level of scientific  
2 evidence, right?

3 MS. KEARSE: Object to form.

4 A. No. I would say this is one of the few  
5 places where we have had such a large cohort of  
6 pharmacologically treated.

7 So the difference between this cohort and  
8 that cohort is that just looked at exposed. This is  
9 looking at treated.

10 Q. Well, so are you familiar with evidence-based  
11 medicine or any of the other standards where you have  
12 kind of a level or classification for the class of  
13 something?

14 A. Sure.

15 Q. So where would this retrospective cohort with  
16 87 infants fall?

17 A. I would have to look at the definitions to  
18 give you the exact letter and number.

19 Q. Okay. But in general, retrospective cohorts  
20 are lower down than prospective studies, particularly  
21 prospective controlled studies, right?

22 MS. KEARSE: Object to form.

23 A. It depends on what you're looking at, because  
24 certain things you can never do a prospective  
25 double-blinded study on.

1           So this is -- a lot of the times,  
2   retrospective studies are fantastic in giving you  
3   baseline data to move forward and develop what you  
4   want to address in a prospective study.

5           Q.   Okay.   So why don't we go to the Subjects and  
6   Methods on page 2.   So it is described as a  
7   "retrospective chart review."

8           Do you see that?

9           A.   Uh-huh.

10          Q.   And it says, "with no parental consent  
11   required."   It was the determination from your  
12   hospital that parental consent was not required to do  
13   this chart review study, correct?

14          A.   Correct.

15          Q.   And then there also -- because of the way  
16   this is set up, there isn't a predetermined control  
17   group, correct?

18          A.   Not in this study, correct.

19          Q.   It continues down towards the bottom of the  
20   page.   It says that, "Data collected..."

21          Do you see this, about a --

22          A.   Yes, "...collected from the neonatal  
23   period..."

24          Q.   Yes.   "...included gender, race, ethnicity,  
25   maternal age, maternal substance use, gestational age,

1 birth weight, breastfeeding, type of treatment for  
2 NAS, length of hospital stay, and with whom the infant  
3 was discharged home."

4 Do you see that?

5 A. Yes.

6 Q. So, did this include any of these  
7 socioeconomic factors that we have talked about that  
8 affect neurodevelopment outcomes according to other  
9 research?

10 A. It just looked at those listed.

11 Q. Okay. So like, mother's educational status,  
12 mother's IQ, any measures of kind of home instability,  
13 none of those factors are looked at here?

14 MS. KEARSE: Object to form.

15 A. Correct.

16 Q. Okay. And it says: Infants were considered  
17 exposed to a substance in utero with maternal urine at  
18 delivery or infant urine, meconium or umbilical cord  
19 toxicology screens were positive for that substance.

20 Do you see that?

21 A. Yes.

22 Q. And obviously, when we are talking about  
23 substances, there is some identification of the  
24 particular drugs at issue, but you don't necessarily  
25 know when they were used and how much they were used,

1 right?

2 A. We know it's last trimester because it is  
3 positive on the urine of the mom or the infant, and  
4 then a meconium and umbilical cord usually are last  
5 trimester, too.

6 Q. Okay. And so that's the most you can do is  
7 it's sometime in the last trimester, but you don't  
8 necessarily know how much they took, specifically when  
9 they took it or how they got what they took?

10 A. Not in this study.

11 MS. KEARSE: Object to form.

12 Q. And so for like how they got what they took,  
13 is this one where there was some cross-referencing to  
14 OARRS to see if there was a prescription?

15 A. No.

16 Q. And there certainly isn't like going back to  
17 see if they were using illicit drugs, how they started  
18 on using illicit drugs?

19 A. That is correct.

20 Q. And it says: Due to universal maternal  
21 toxicology screening in our region, all mothers and  
22 infants had toxicology screens.

23 Do you see that?

24 A. Yes.

25 Q. "Infants were considered exposed to poly

1 substances if they were exposed to drugs from more  
2 than one class."

3 So I take it if they were exposed to a bunch  
4 of drugs within one class, it wasn't considered poly  
5 substance for this study?

6 A. So it was an opioid plus something else,  
7 because they had to be opioid exposed to be in this  
8 clinic.

9 Q. But if they were taking like heroin and  
10 fentanyl and, you know, some -- some other street  
11 drug, those would all just show up as opioid, not  
12 polypharmacy?

13 A. Depends on what street drug you're referring  
14 to.

15 Q. I'm sorry. Some other opioid or opiate  
16 street drug.

17 A. So if it was an opioid, it would just be  
18 classified as an opioid.

19 Q. Okay. Go to the Results section. It says:  
20 All mothers were Caucasian with a median maternal age  
21 of 26 years, which reflects the demographics of the  
22 opioid epidemic in our area.

23 What does that mean? This is the second  
24 paragraph under results.

25 A. I see that.

1           So "all" is not a correct statement because I  
2   think our paper showed 92 percent. So I think that a  
3   better word would have been -- so I think "all" was  
4   the result, but the demographics, meaning that it is a  
5   mainly Caucasian disease that we're seeing is what  
6   they're referring to.

7           Q. So the -- I guess go backwards to be  
8   complete. The birth weight here of 2.87 kilograms and  
9   that 14 percent were the first decile, is that kind of  
10   within the normal range of birth weights?

11          A. So three kilos is the average, so -- and this  
12   2.87 is very consistent with what we found in our  
13   first OCHA study.

14          Q. I'm asking a slightly different question.  
15   So this birth weight in terms of the median and the  
16   percentage in the first decile, is that consistent  
17   with the range of expected birth weights for nonopioid  
18   exposed infants?

19          A. It's a little bit lower.

20          Q. And there are various reasons for low birth  
21   weight, including various aspects of maternal care  
22   throughout the pregnancy, right?

23          A. There is multiple reasons for lower birth  
24   weight.

25          Q. You're not attributing that just to the

1     opioid or opiate exposure, correct?

2             A.    Correct.

3             Q.    Median gestational age was 38 weeks, a range  
4     of 31 to 41, with four babies born at 34 weeks, one at  
5     35 and six at 36.

6             Is that fairly typical in terms of when the  
7     children are being born compared to a normal  
8     population for this area?

9             A.    I think our norm -- I only know statewide  
10    data. I think it is 38 weeks is the median; but 38 --  
11    I don't think this is statistically different than  
12    what our normative is.

13            Q.    So not really born very early?

14            A.    Correct.

15            Q.    Okay. Says "Almost all of our women..." --  
16    this is after the statement about how they were all  
17    Caucasian -- "used illicit substances during  
18    pregnancy. The majority were on therapy with  
19    Methadone 38 percent or buprenorphine 24 percent at  
20    the time of delivery."

21            So what did it tell you that they were all --  
22    they -- almost all of them had used illicit  
23    substances during the pregnancy?

24            A.    I don't know. I would have to look at their  
25    table. As I said, I'm not an author on this. I just



1 reviewed the writing, so I would have to look at  
2 Table 1.

3 Q. Table 1 is actually at the penultimate page,  
4 after the figures.

5 A. So Table 1 lists heroin as 67 percent. So --

6 Q. And these go to more than a hundred, right?  
7 There is --

8 A. I don't know how -- if it was -- one of the  
9 -- so if you had a mom that had -- could be positive  
10 for more than one, I don't think that this -- looking  
11 back at this paper now that it has been published.

12 So if had you polysubstance abuse, you could  
13 have heroin, cocaine, benzodiazepine. So those  
14 numbers would be one patient but it would be three  
15 tics. So just because the heroin, cocaine and  
16 benzodiazepines, marijuana, all that is over a hundred  
17 percent if you look -- add those together.

18 So I don't know where they got that  
19 information from.

20 Q. Just looking at it, two-thirds of the women  
21 in this study were using heroin while pregnant, right?

22 A. That's what is showing in this, yes.

23 Q. What does that tell you about what we were  
24 talking about earlier, about how the patients who may  
25 be at -- medically assisted treatment by the time

1 they're delivering are using illicit substances while  
2 pregnant as well?

3 MS. KEARSE: Object to form.

4 A. Yeah, it shows that it's happening.

5 Q. And it suggests that -- well...

6 These are also fairly high use of wide range  
7 of drugs while pregnant, not just drugs as part of  
8 medical treatment to try to get them through the  
9 pregnancy, right?

10 MS. KEARSE: Object to form.

11 Q. Not just MAT?

12 A. Right. So I think the MAT is 54 patients, so  
13 that would attribute to a little over the -- looks  
14 like that was at 60 percent, like we were talking  
15 about.

16 Q. That's basically the -- you add up the  
17 methadone and the buprenorphine?

18 A. Correct.

19 Q. For 62 percent?

20 A. Yes, that was sort of our estimate I think we  
21 were doing earlier.

22 Q. Okay. So going back to where we were.

23 The -- that almost all the woman were using  
24 illicit substances, including predominantly heroin,  
25 while pregnant, does this tell us anything about the

1 role of illicit substances used during pregnancy in  
2 relation to the NAS babies that you do see?

3 MS. KEARSE: Object to form.

4 A. So it depends on when this illicit use was.  
5 If it was in first trimester, before they got  
6 pregnant, that would count. So I don't know what the  
7 effects it would have.

8 Q. I mean, it says "during pregnancy" here, it's  
9 not --

10 A. It doesn't state when during the pregnancy,  
11 correct.

12 Q. All right. So it continues down to the next  
13 page, talking about some of the data about how they  
14 were -- the infants were treated, how long they  
15 stayed. And then it says: Child Protective Services  
16 were involved in all cases.

17 Do you see that?

18 A. Yes.

19 Q. And is that unusual in your population?

20 A. No. Because anytime we have a positive  
21 toxicology test, we involve social services,  
22 especially if it is an opioid.

23 Q. Only 26 percent -- percent of the infants  
24 went home in the primary care of their mother.

25 Do you see that?

1 A. Yes.

2 Q. Thirty went home in primary care of the  
3 father or another relative, and 44 percent went home  
4 to -- in foster care or with an adoptive facility.

5 Now, that determination is made by the social  
6 services or Child Protective Services, not by any of  
7 your staff, correct?

8 A. It is a team approach, but, yeah, they make  
9 the final decision.

10 Q. And is this fairly typical in your patient  
11 population, that you're going to see about 44 percent  
12 of the kids going home with -- to foster care or  
13 adoptive family rather than the mother or any  
14 relative?

15 A. This is much higher than what we see  
16 statewide and in our region. So that's usually just  
17 20 percent.

18 So this is -- showed that to -- and I think  
19 that's where we get to the compliance of coming to the  
20 -- was much higher with adoptive families, and that's  
21 why they were able to participate in this  
22 retrospective review. So this is a different  
23 population than what we are seeing in the general.

24 Q. And this issue of going to an adoptive family  
25 or foster care, can that itself have an effect on

1 Bayley scores?

2 A. We don't know. We just know in this cohort  
3 study that -- which is much higher than our regular  
4 percentage of patients that go into foster care, they  
5 did perform better.

6 Q. So the paragraph that carries over from page  
7 3 to page 4, it says: Most children have Bayley  
8 scores within the normal range for all three  
9 subscales, although a large proportion did have scores  
10 at least one standard deviation below the mean in at  
11 least one subscale.

12 Do you see that.

13 A. Yep.

14 Q. Can you translate that to English?

15 MS. KEARSE: Object to form.

16 A. Layman's term, you mean?

17 Q. Sure.

18 A. Because it is English.

19 So one standard deviation is what we would  
20 expect to be a normative Bell-shaped curve. So if you  
21 fall within that, you can still be statistically  
22 within the norm, but you may be -- which we talk about  
23 later on -- they talk about later on -- is  
24 significantly -- statistically significantly lower.

25 So this four-point difference falls within

1 the standard deviation of 15, meaning anything between  
2 85 and 115 is our normative; but if you can show there  
3 is a decrease, it just is a fact, it doesn't mean -- I  
4 don't -- nobody knows what this four-point difference  
5 means.

6 Q. Okay. So compared to some other exposures or  
7 inputs or factors that affect Bayley scores, this is a  
8 relatively mild deviation from the norm in a subset of  
9 the things being tested?

10 MS. KEARSE: Object to form.

11 A. I don't know what adjective I would use. It  
12 is just significantly lower. But long-term, I don't  
13 think anybody knows what that four points is going to  
14 mean.

15 Q. Okay. So it says: Compared to the normative  
16 Bayley data, mean of 100 standard deviation of 15,  
17 children with NAS scored significantly lower on the  
18 cognitive language and motor subscales, means of 96.5,  
19 93.8 and 94.0, respectively, P less than 0.03 for all.

20 Do you see that?

21 A. Yes, I do.

22 Q. The word "significantly" there means  
23 statistically significantly, correct?

24 A. Yes.

25 Q. It is not saying there is a known clinical

1 significance to this?

2 A. That is referring to the statistical  
3 significance.

4 Q. And what I said is also true: That it is not  
5 known that there is clinical significance to any of  
6 these levels of difference?

7 A. It is unknown if this means anything long  
8 term.

9 Q. And then it says: Children who live with  
10 foster/adoptive families at follow-up, which is 44  
11 percent, scored significantly higher on the cognitive  
12 subscale than those who live with their mother or a  
13 biological relative at a follow-up.

14 Do you see that.

15 A. I do.

16 Q. And again, that's like statistically  
17 significant .03 for the P value, right?

18 A. Correct. That means they actually scored the  
19 exact average in the foster family of a hundred.

20 Q. And it says: Language scores were not  
21 different based on living situation, but children who  
22 live with biological relatives were also slightly more  
23 likely to have motor scores under 85.

24 Do you see that?

25 A. I do.

1           Q. So putting it together, what does this issue  
2 tell us about the more normal scores, if you will, of  
3 people placed with a -- children placed with foster or  
4 adoptive families versus being with their mother or a  
5 biologic relative?

6           A. It means they scored better on their Bayley's  
7 -- their Bayley's testing.

8           Q. Do you have a supposition as to why that  
9 would be?

10          A. It is unclear.

11          Q. Have you considered the possibility that is  
12 what we saw in all of these other papers where it says  
13 that other factors, like the mother's view of  
14 parenting, her educational level, the uncertainty in  
15 the family, all of these other factors that aren't  
16 adequately covered just by income level might be  
17 playing a role?

18          A. It is multifactorial, so some of that  
19 definitely comes in. I don't think we have the income  
20 level of the foster families or their socioeconomic  
21 status. So I think that's where it gets tricky.

22          Q. And I don't mean to be mean at all, but in  
23 general: A child placed with an adoptive family in  
24 this situation going from a population that is about  
25 90 percent on Medicaid is not typically going to a



1 worse financial situation or socioeconomic status than  
2 where they came from?

3 MS. KEARSE: Object to form.

4 A. I wouldn't know the socioeconomic status of  
5 our adoptive families.

6 Q. You think they're likely to be on Medicaid?

7 MS. KEARSE: Object to form.

8 A. They -- I wouldn't have any -- I don't know.  
9 I don't -- it wouldn't surprise me if some were.  
10 Yeah.

11 Q. So will you agree that, in general, the  
12 children placed with a foster or adoptive family are  
13 going to go to a family situation that is expected to  
14 be more stable and more nurturing than the mother from  
15 whom social services removed them?

16 MS. KEARSE: Object to form.

17 A. I think there is a significant background  
18 check on adopt -- foster families to make sure that it  
19 is a safe environment for them.

20 Q. So in other words, you would hope so, right?  
21 You would hope they're going to a better situation?

22 A. Yes.

23 MS. KEARSE: Object to form.

24 Q. And those measures of a better situation,  
25 including things like food on the table and less

1 chance of being exposed to traumatic events and  
2 violence are what you would hope to see when there is  
3 a successful placement, right?

4 MS. KEARSE: Object to form.

5 A. That is the whole premise behind foster  
6 system.

7 Q. And you would expect that those things would  
8 have an affect on Bayley scores?

9 A. I think this is the first study to look at  
10 that, so it is definitely something that we --  
11 definitely is intriguing and that would need further  
12 investigating.

13 Q. You would expect that they would have an  
14 affect on -- whether it is Bayley scores or anything  
15 else -- on neurodevelopment outcomes?

16 A. The expectation is that it would be  
17 beneficial, and -- so, yes.

18 Q. So the indications in this paper of a slight  
19 increased deviation from the norm in the children who  
20 had NAS diagnosis was overwhelmingly driven by the  
21 ones who stayed with their mother or a family relative  
22 despite the social services evaluation, correct?

23 A. In this population, so this, as they stated,  
24 was very high illicit substance use, which as I stated  
25 previously is not our normative generalized NAS.

1 Q. So we go to the Discussion, it says: In this  
2 retrospective study, we evaluated outcomes at two  
3 years of age of a regional cohort of infants treated  
4 for NAS due to maternal opioid use.

5 As we see largely driven by heroin use,  
6 correct?

7 MS. KEARSE: Object to form.

8 A. It just states "maternal opioid use," which I  
9 think majority were MAT.

10 Q. We found that children with NAS performed  
11 lower than the normative Bayley sample, although still  
12 within the normal range in most cases.

13 Do you see that?

14 A. Yes.

15 Q. Is that an accurate statement?

16 A. Yes.

17 Q. It says: We do believe that the four- to  
18 six-point difference in Bayley scores is clinically  
19 significant, although it is difficult to say whether  
20 this will translate into later problems with school  
21 performance or IQ.

22 Do you see that?

23 A. I do.

24 Q. And as we said, this four- to six-point  
25 difference is driven solely by the ones -- the

1 children who stayed with the mother or a family or a  
2 relative, correct?

3 A. You're compounding multiple different things,  
4 so, if you --

5 Q. I'm actually just doing the math, but because  
6 there is no difference in the other group, this four-  
7 to point-six difference has to come from a greater  
8 than four- to six-point difference in the group that  
9 stays with their mother or a relative?

10 MS. KEARSE: Object to form.

11 A. So the ones with foster didn't have a  
12 decrease in all three categories, which the main group  
13 did, so there is some overlap. So you couldn't solely  
14 base it on foster because then you would have seen a  
15 decrease in all three, which you don't.

16 Q. For some reason, language isn't as directly  
17 correlated, right?

18 A. Yeah. So this is their discussion which  
19 doesn't mean it is always a hundred percent correct.  
20 If you can look back and show -- have the result or  
21 the way you're interpreting it.

22 Q. Okay. So why don't we go to the next page,  
23 page 5. There is the third paragraph, second full  
24 paragraph on that page, it says: The mechanism behind  
25 neurodevelopmental delays in children exposed to

1     opioids in utero and postnatally is not entirely  
2     clear.

3             Do you see that?

4             A.   I do.

5             Q.   Discussion -- discusses some stuff about  
6     possible mechanisms. And then it says: Our finding  
7     of higher cognitive scores in children raised by  
8     foster/adoptive families suggest that socioeconomic  
9     factors do significantly affect outcomes in this  
10    population.

11            Do you see that?

12            A.   I do.

13            Q.   Do you agree with that statement?

14            A.   Not a hundred percent, but I do see that it  
15    improves some aspects.

16            Q.   Okay. Why don't we go to the next page,  
17    please.

18            It says: We acknowledge that our study has  
19    significant limitations notably the retrospective  
20    observational design.

21            Do you see that?

22            A.   Yep.

23            Q.   We did not have a control group and we did  
24    not have the accurate information on socioeconomic  
25    status of the families.

1 Do you see that?

2 A. I do.

3 Q. And how could not having accurate information  
4 on socioeconomic of the families affect the results?

5 A. Because we know that socioeconomic status  
6 does have an effect on developmental outcomes.

7 Q. Of all the children with NAS in our region,  
8 only about 25 percent actually had a Bayley performed  
9 due to caregiver preference/no-shows which could have  
10 led to selection bias.

11 What does "selection bias" mean in this  
12 context?

13 A. Meaning that if you get all of the foster  
14 families to show up and agree and consent to the  
15 testing, you are going to have families that are more  
16 motivated and doing more interventions, most likely,  
17 that may elevate that score section, whereas the ones  
18 from the nonfoster family may only be consenting for  
19 other reasons.

20 Q. You agree with this observation about this is  
21 a potential source of selection bias, correct?

22 A. Yes.

23 Q. Our findings could well be due to the  
24 postnatal environment experienced by these children  
25 and warrant a prospective study using standardized

1 measures of behavior and visual functioning in  
2 addition to neurodevelopment as well as standardized  
3 data collection of socioeconomic status.

4 Do you see that?

5 A. I do.

6 Q. Do you agree with that statement?

7 A. I do agree.

8 Q. And is that prospective study underway?

9 A. That is what we have applied for the grant  
10 for, yes.

11 Q. Okay. So you are going to use standardized  
12 measures of behavioral and visual functioning, and  
13 standardized data collection on socioeconomic status?

14 A. That is what we discussed, yes.

15 Q. So sitting here today given the need for  
16 further research and these various observations about  
17 the limitations of the design, you don't think that is  
18 Merhar paper establishes neurodevelopment delays with  
19 neonatal abstinence syndrome, do you?

20 MS. KEARSE: Object to form.

21 A. I think it shows that there is a significant  
22 difference, a decrease. And what that means is  
23 unknown and that we need to further investigate to see  
24 if there isn't a true association.

25 Q. And it may not last past the time period

1 studied in this paper, right?

2 A. Correct.

3 Q. I mean the -- sometimes differences seen  
4 early in life normalize, right?

5 MS. KEARSE: Object to form.

6 A. If you can do early intervention. The whole  
7 idea is to identify infants at risk and then get them  
8 into early intervention, which we know does help with  
9 long-term outcomes.

10 Q. Okay. Why don't we go to the next paper.

11 Do you have that in front of you? The Hall  
12 paper that you are on.

13 A. Yes.

14 Q. So you said that this was published in full  
15 form earlier this year but it had been public in some  
16 form last year, which is why it appears on your  
17 presentation with a 2018 date, correct?

18 A. Correct.

19 Q. Let me just go to the end here. Author  
20 Disclosure Statement.

21 Do you see that see?

22 A. Yes.

23 Q. On the -- page 23 -- it is not actually 23,  
24 it starts on page 19. It is just fifth page of the  
25 actual printout.



1 But this is a statement that is a disclosure  
2 of possible conflicts and biases for you and the other  
3 two authors, correct?

4 A. Correct.

5 Q. And do you disclose here, Dr. Wexelblatt,  
6 that you're currently engaged as an expert witness for  
7 plaintiffs in opioid litigation?

8 A. At this time, I wasn't.

9 Q. It was published this year?

10 A. It was submitted well before this.

11 Q. So when did you have the last exchange in  
12 terms of addressing any peer review comments or doing  
13 any revisions or resubmissions for this paper?

14 A. When it was accepted for e-publication in  
15 2018 before whatever month that was on the original.

16 Q. Okay. So going forward, are you going to  
17 disclosure your work as an expert in this litigation  
18 on other papers that relate to opioids?

19 A. Yes. Now that it is part of this, correct.

20 Q. Okay. And so what about when you present  
21 publicly anytime this year because you said you were  
22 retained what, December of last year, correct?

23 A. December, correct.

24 Q. So since December, since you were retained,  
25 have you disclosed in any public forum when giving a

1 speech or presentation that you are working as an  
2 expert for plaintiffs in opioid litigation?

3 A. I have come to the -- since that time, I've  
4 only given one talk at the Tristate Symposium, and I  
5 think when we had to hand in our slides for that it  
6 was probably right around the time, so I don't  
7 remember if I did disclose that or not.

8 Q. I mean, if we look at slides and there's no  
9 disclosure, does it mean you didn't disclose it or  
10 just didn't make it onto the slides?

11 A. It would just mean didn't disclose it.

12 Q. So what about any of your grants this year?  
13 You submitted grant proposals, right?

14 A. Yes. So those are all listed, and we keep a  
15 database at Cincinnati Children's Hospital for  
16 disclosures.

17 Q. Okay. So all of your grant proposals so far  
18 this year and going forward, like the ones you are  
19 working on right now, will disclose that you're an  
20 expert for plaintiffs, and I guess In Re: National  
21 Prescription Opiate Litigation?

22 A. It will.

23 Q. Have you done that so far in anything that  
24 has been filed, do you know?

25 A. No, I have not.

1 Q. Had you thought of it before today?

2 A. So expert witness is not always a conflict of  
3 interest listed for medical malpractice, but I guess  
4 this is -- I would discuss it with our IRB to see if  
5 we usually disclose everything.

6 Q. Dr. Wexelblatt, so this is the paper that you  
7 mentioned about. We've talk about this before.

8 Hall, as the lead author on the paper,  
9 Developmental Disorders and Medical Complications  
10 Among Infants with Subclinical Intrauterine Opioid  
11 Exposures.

12 So what are the comparison groups in this  
13 paper?

14 A. So there is three main groups. The first one  
15 was the 14,933 was based out of our primary care  
16 clinic at Cincinnati Children's Hospital and they had  
17 no opioid exposure.

18 The middle group is those with opioid  
19 exposure without NAS, meaning they did not need  
20 pharmacologic treatment.

21 And third group is opioid exposure with  
22 pharmacologic treatment.

23 Q. Okay. So was there any attempt to look at  
24 those different groups based upon socioeconomic  
25 status, maternal education, any of the various issues

1 that we have been discussing throughout about other  
2 things that could be tracked in research?

3 A. We did look at insurance type.

4 Q. Okay.

5 A. Race and ethnicity.

6 Q. And you know enough from the work that you  
7 have done that there are factors about the likelihood  
8 of abusing opioids and using illicit opioids that are  
9 broader than just insurance type and race, right?

10 MS. KEARSE: Object to form.

11 A. Yes.

12 Q. And like from -- well, so is there any data  
13 that says that these three groups are similar except  
14 for opioid exposure and NAS diagnosis?

15 A. There -- are they -- the question is: Are  
16 they similar? Is that what you asked me?

17 Q. So I mean, you can go to the next page,  
18 page 22, where it gives the Demographics and Birth  
19 Characteristics.

20 A. Yeah.

21 Q. And there are some differences in terms of  
22 percentages between the three groups?

23 A. Correct.

24 Q. And obviously, one is really big and then the  
25 other two are -- are small with NAS being about, I

1 guess, what, 28 percent or so of the exposure without  
2 NAS?

3 A. So those are two separate groups --

4 Q. Right.

5 A. -- so they're separate.

6 Q. Right. I'm saying it is much smaller,  
7 therefore, it is hard to make direct comparisons with  
8 groups of this size?

9 MS. KEARSE: Object to form.

10 A. It is what we see. It probably ends up --  
11 just doing the quick math -- what we see in our region  
12 with around a 30 percent exposure with treatment rate.  
13 So it should be less because not all of your exposed  
14 babies are being treated in our region.

15 Q. Did you determine any differences based upon  
16 the information you did have about type of insurance,  
17 race and ethnicity that indicated there were  
18 differences between the three groups?

19 A. Yeah. We didn't do a statistical analysis to  
20 -- it was more of just a -- of a descriptive what  
21 those groups were.

22 Q. Right. I mean, the stats probably wouldn't  
23 be that hard to do?

24 A. Correct.

25 Q. And for some reason, they weren't done

1 here?

2 A. Yeah, I don't know.

3 Q. But if you look at it, the public or self-pay  
4 among the nonexposed group is 50 percent, which is  
5 similar to the state average?

6 A. Correct.

7 Q. And the public or self-pay among opioid  
8 exposure without NAS was 84.6 percent, which is  
9 similar to what you see for NAS around the state, but  
10 indicates a much higher poverty percentage in this  
11 group, correct?

12 A. Correct.

13 Q. And in opioid exposure with NAS, it's 95.7  
14 percent, which is even higher than statewide for NAS  
15 which indicates a strong correlation of poverty to not  
16 just opioid exposure, but sufficient opioid exposure  
17 to cause NAS, right?

18 A. Correct.

19 Q. I mean, this is pretty easy math and stats to  
20 do if somebody chose to put it in a paper.

21 A. Correct.

22 MS. KEARSE: Object to form.

23 Q. Why wasn't it in the paper?

24 A. I don't know why the P value -- I know we had  
25 that listed, and I don't know if the table just never

1 -- as we do papers, there is multiple revisions.

2 And I know at one time we did have the  
3 P value, and I don't know why in the final publication  
4 it didn't get there

5 Q. Oh, so have you those P values somewhere,  
6 right?

7 A. I thought we did at one point in one of our  
8 versions. I would have to go back to Dr. Hall and see  
9 where -- where those were.

10 Q. Okay. And I mean, we don't have to go  
11 through this whole thing, but there are also  
12 differences in race and ethnicity between the  
13 different groups, right?

14 Like, for instance, non-Hispanic White in the  
15 opioid exposure with NAS is almost 60 percent, which  
16 is way higher than the other two groups?

17 A. Correct.

18 Q. So these groups are not similar?

19 A. Correct.

20 Q. So there is plenty of reason just on the  
21 limited demographic information you have about  
22 socioeconomic status and demographics to expect that  
23 you are going to have worse scores with the opioid  
24 exposure and NAS groups?

25 MS. KEARSE: Object to form.

1           A. On certain subjects, you should expect that,  
2 but on others you shouldn't.

3           Q. Okay. We don't know what other differences  
4 there might be between these groups that might  
5 independently suggest an increased risk of some of  
6 these deficits.

7           A. So torticollis and strabismus and  
8 plagiocephaly would have nothing to do with -- that's  
9 ever been stated, to my knowledge, based on  
10 socioeconomic status.

11          Q. So let me break it out for the -- frankly, we  
12 have been really focusing on, which is issues like  
13 developmental delays, behavioral and emotional  
14 disorders, those issues, there may be confounding  
15 factors that are more common in the exposed groups  
16 than in the no detected exposure group, right?

17           MS. KEARSE: Object to form.

18          A. Those would be higher in the exposed group,  
19 is what you stated, compared to no detected?

20          Q. I said this may be factors that this paper  
21 wasn't able to pick up that would cause higher  
22 behavioral problems, emotional problems, developmental  
23 delays, having --

24          A. That is a limitation, correct.

25          Q. -- nothing to do with exposure?



1 A. Correct.

2 Q. Same thing for HCV exposure, too, right?

3 A. I don't think so. I don't know if there is  
4 much information on hepatitis C exposure and  
5 socioeconomic status that hasn't been associated with  
6 opioid use.

7 Q. Well I mean, there is people who share  
8 needles versus people who don't, right? And that does  
9 have data suggesting it's more likely to have needle  
10 sharing in certain socioeconomic groups compared to  
11 others?

12 A. Could be.

13 Q. I mean, I'm not making this stuff up out of  
14 thin air, right?

15 A. No.

16 Q. These are all issues that, frankly, are  
17 limitations on the study?

18 MS. KEARSE: Form.

19 A. Correct. We state our limitations,  
20 definitely.

21 Q. Well you state some of your limitations. You  
22 don't state any of the stuff that I just mentioned.

23 We'll get to the stated limitations on  
24 page 23 in a second.

25 A. Okay.

1 Q. Let's just go through this, I guess, probably  
2 a little more directly.

3 Result section, page 21, it says: In  
4 comparison to infants with no detected exposures,  
5 those with opioid exposure but no NAS were  
6 significantly more likely to be diagnosed with  
7 behavioral or emotional disorders, developmental  
8 delay, exposure to HCV, speech disorder and  
9 strabismus.

10 That's one of the findings that you have  
11 cited on this -- for this paper, correct?

12 A. Correct.

13 Q. It says: Opioid exposed infants without NAS  
14 were significantly less likely to be diagnosed with  
15 developmental delay, exposure to HCV, plagiocephaly,  
16 sensory disorders, strabismus or torticollis than  
17 opioid exposed infants who experience NAS.

18 Meaning basically as you go forward from  
19 exposure without NAS to exposure with NAS, you had  
20 even worse results?

21 A. Correct.

22 Q. Again, that also follows the trend of what we  
23 have seen in terms of socioeconomic status and perhaps  
24 some of the other indicators in this paper about  
25 differences between the groups, right?

1           A. A lot of confounders, correct.

2           Q. Compared to infants with no detected  
3 exposure, the diagnosis of developmental delay was  
4 highest among infants with NAS, 7.6 percent versus  
5 28.3 percent. However, the diagnosis was still twice  
6 as likely among opioid exposed infants without NAS,  
7 7.6 compared to 15.6.

8           So it's, again, one of the findings you cited  
9 with this paper, right?

10          A. Correct.

11          Q. Okay. It says: After correction for  
12 multiple comparisons within the sensitivity analysis  
13 of 8,049 Medicaid insured or self-paying patients,  
14 rates were no longer statistically different comparing  
15 opioid exposed infants without NAS to infants with no  
16 detected exposures for the diagnoses of behavioral or  
17 emotional disorders and speech disorder.

18           Do you see that?

19          A. I do.

20          Q. Okay. Correct me if I'm wrong, but what that  
21 means is once you account for the one thing we have  
22 here about socioeconomic status, which is insurance,  
23 that there is actually no difference for the exposed  
24 group without NAS for those measures?

25          A. When you do the multiple comparisons,

1 correct.

2 Q. The one sort of adjustment for a confounding  
3 factor that is known shows that the difference goes  
4 away in the exposure without NAS group, correct?

5 A. Correct.

6 Q. And so for your view, this paper can't  
7 possibly stand for the position that exposure, opioid  
8 exposure without NAS increases the incidence of  
9 behavioral or emotional disorders or speech disorder,  
10 correct?

11 MS. KEARSE: Object to form.

12 A. So that is looking at the middle group.

13 Q. Yes, that was the question.

14 A. Not the final -- those with NAS.

15 Q. Correct, that was my question.

16 A. So if you're looking at opioid exposure  
17 without NAS, then that is correct. But if you say  
18 with NAS, we never -- that statistical significant is  
19 still seen.

20 Q. And where is that data shown?

21 A. Significance of all other associations remain  
22 unchanged (data not shown.)

23 Q. Yeah. Where is that math? Where is that  
24 data shown about what happens when you correct for  
25 socioeconomic status and Medicaid payment?

1           A. So we state the one that -- we state that  
2   opioid exposed infants without NAS. It didn't make  
3   that go away. But when you did with NAS, it didn't.

4           Q. What is the P value when you adjust for  
5   Medicaid status?

6           A. We don't show all of that data, but it stayed  
7   -- it was significant.

8           Q. Where is that data?

9           A. It's in a computer somewhere.

10          Q. Have you ever presented the full data from  
11   this paper like at a public presentation?

12          A. We had the data presented to the reviewers of  
13   this journal that felt it was sufficient and  
14   adequate.

15          Q. So my -- that's kind of -- my question is:  
16   You mentioned that there was something that maybe was  
17   in the paper before it finally got published for the  
18   last paper.

19                 Do you have copies of the -- what was  
20   submitted for publication in this Hall paper?

21          A. I personally don't, but I know Dr. Hall  
22   does.

23          Q. What about the prior one that we went over  
24   from your colleagues from the Merhar paper, do you  
25   have a copy of what they asked you to review that got

1 submitted?

2 A. No, I don't.

3 Q. Do we know if there is data that was included  
4 in what got submitted to the journal that didn't make  
5 its way into the final publication in the Hall  
6 paper?

7 A. I do not know that.

8 Q. So what was the P value for behavioral,  
9 emotional disorders and speech disorder for the NAS  
10 group once you accounted for Medicaid insured or  
11 self-paying status?

12 A. They remained unchanged per that statement  
13 significant -- significance of all other associations  
14 remained unchanged. So they didn't change.

15 So that's why they were not shown because  
16 there was no difference in the P values, whereas the  
17 P values did change in the other ones.

18 Q. I mean, what you are looking for there is  
19 whether the P value crosses the threshold for .05,  
20 right?

21 A. So if it's unchanged, it's what's published  
22 right there in the unadjusted variables here.

23 Q. Well, it doesn't say that. I don't mean to  
24 pick, but it says "significance of all other  
25 associations," it doesn't say the P value didn't

1 change.

2 A. The significance -- so that's just the  
3 definition of what significant of .05.

4 Q. Yes. So my question to you was: Do you know  
5 what the P value was once the adjustment was done?

6 A. It was under .05.

7 Q. And data should exist somewhere with  
8 Dr. Hall?

9 A. It is listed in B, the preadjustment, but --

10 Q. I'm asking about the adjusted data. Is that  
11 with Dr. Hall?

12 A. Yes --

13 MS. KEARSE: Objection.

14 A. -- I assume it is with him.

15 Q. Okay. I mean, I didn't -- I didn't know if  
16 it was with Dr. McAllister, so --

17 A. No. Dr. Hall is the bio informatics.

18 Q. Okay. The discussion says: The study team  
19 is unaware of previous studies focusing specifically  
20 on diagnoses among opioid exposed infants who did not  
21 express severe signs of withdrawal, most likely  
22 because of difficulty in identifying these infants  
23 without a universal mechanism for maternal drug  
24 testing.

25 Is that still the case: You are unaware of

1 any other study that has this possible finding?

2 A. Correct.

3 Q. So this -- this study is kind of out on its  
4 own as addressing these issues and having the findings  
5 that, at least before they were adjusted, showed  
6 increase, but after they were adjusted showed no  
7 increase in this group?

8 MS. KEARSE: Object to form.

9 A. So the only things that didn't stay  
10 significant were those two things that we list there,  
11 but the other ones did stay significant.

12 Q. Okay. So let me ask it more directly then:  
13 This -- is this the only study that you are aware of  
14 that has the findings of increased risk of any of  
15 these issues with opioid exposure without NAS?

16 A. Yes. So the significance changed for  
17 behavioral and emotional disorders and speech  
18 disorders, but they didn't change for the other things  
19 that we state, like hepatitis C, sensory disorders,  
20 strabismus and torticollis.

21 Q. Okay. So why don't we go to the next page.  
22 It says: There was notable limitations to this  
23 analysis -- this is page 23, it says: including  
24 limitations inherent to the retrospective study  
25 design. Although opioid exposure was identified using



1 universal testing, details of exposure extent and  
2 duration were unavailable.

3 Do you see that?

4 A. Yep.

5 Q. And we have talked about that as an issue  
6 with the database that you have and how it might  
7 affect your study results more generally, correct?

8 MS. KEARSE: Object to form.

9 A. That is true.

10 Q. Neither did the study team have access to a  
11 detailed profile of any polysubstance exposures.

12 Do you agree with that, too, right?

13 A. I do.

14 Q. Variability in exposure characteristics may  
15 contribute to variation and rates of developmental  
16 diagnoses and medical complications. It is possible  
17 that diagnosis rates underrepresent true incidence of  
18 the conditions studied as children lost to follow-up  
19 would not have been assigned diagnoses within this  
20 CCHMC EHR.

21 To minimize the effects of any potential  
22 differential in children lost to follow-up,  
23 sensitivity analysis was conducted of Medicaid insured  
24 and self-paying patients who were not likely to seek  
25 care through the CCHMC system. Although diagnoses of

1 behavioral or emotional disorders and speech disorder  
2 were no longer statistically significant after  
3 correction for multiple comparisons, based upon the  
4 small P values, less than .05, it is possible those  
5 differences would be significant given a larger cohort  
6 of opioid exposed infants.

7 So, I'm looking through the limitations that  
8 are described. Is there any limitation that is  
9 described along the lines of what we went over  
10 earlier?

11 A. Besides the -- what we adjusted for was the  
12 Medicaid, which would adjust for the socioeconomic  
13 status.

14 Q. I mean, shouldn't this have said, we -- we  
15 have concerns that any conclusions about the opioid  
16 exposure without NAS and opioid exposure with NAS  
17 findings are invalid because of the significant  
18 differences between our three groups?

19 MS. KEARSE: Object to form.

20 A. No.

21 Q. Okay. Should it have at least raised that as  
22 a direct concern about a limitation of the study?

23 A. No, because we -- once you adjusted for  
24 Medicaid, we only saw changes in two of the multiple  
25 things that we were looking at. So majority of things

1 that we looked at didn't have significant changes.

2 Q. So this continues, as these papers often do,  
3 with a statement about kind of future work.

4 It says: The study team plans to validate  
5 these initial findings to further characterize risk  
6 factors for developmental delays and complications and  
7 to develop a standardized screening schedule for  
8 earlier detection and referral of these high-risk  
9 infants through enrollment and analysis of a  
10 prospective cohort.

11 Do you see that?

12 A. I do.

13 Q. So these were not validated findings yet,  
14 correct?

15 A. No. It means that's what we found in that  
16 retrospective review. The results speak for  
17 themselves. What we want to do is go prospectively  
18 with a control group, which we mentioned multiple  
19 times, to see what happens once you do it that way.

20 Q. And do you have an idea when that research  
21 will be concluded?

22 A. That's the grant that we have applied for and  
23 we are still waiting on the funding for that.

24 Q. If you get the funding, when will that  
25 research be concluded?

1           A. It is a two-year enrollment, so it would  
2   enroll for two years and wait for -- we don't do the  
3   Bayley's -- these testing until two years of age, so  
4   it would be a four-year study.

5           Q. Okay. Okay. So data might be made available  
6   in some way in maybe 2023 and maybe published in maybe  
7   2024?

8           A. If that's the time line.

9           Q. Okay. So until then, there won't be, as far  
10   as you know, prospective reliable data about  
11   differences relating to developmental delays  
12   associated with opioid exposures in utero?

13           MS. KEARSE: Object to form.

14           A. No, because we have ongoing study as part of  
15   our NAS follow-up clinic that is under -- that  
16   development of the clinic is to continue to enroll  
17   patients.

18           And we always do -- we -- Bayley scores are  
19   not part of the normative, so we enroll patients to do  
20   that. So it is an ongoing thing that we had done  
21   since the establishment. So we have ongoing data that  
22   we are collecting.

23           Q. Have you written to ACOG and told them that  
24   you thought that their summary of the issue of  
25   long-term effects from opioid exposure in utero are

1 wrong or were presented in any kind of public forum by  
2 sending in a letter to the editor or commenting on  
3 somebody else's publication, anything to that effect,  
4 to say that the many, many, many statements that are  
5 out there that say that there is no data showing  
6 long-term effects are, in fact, wrong because of more  
7 recent research at your institute, sir?

8 A. I have not wrote any letters to any  
9 committees.

10 Q. Or spoken publicly along the lines of, you  
11 know, the data now establishes something different  
12 than what is generally put forward in review articles  
13 and committee opinions?

14 A. So there is a large grant, which I'm not a  
15 part of, that is submitted by Health and Human  
16 Services that is addressing this exact issue.

17 Based on initial data that -- that -- the  
18 NCIA -- the NIH is funding, looking at enrolling  
19 patient with NAS to do MRIs and Bayley's to  
20 definitively answer this question. So that is a  
21 multi-center trial that is being funded, and we should  
22 know in July.

23 Q. Who is taking the lead on that, as far as you  
24 know?

25 A. It is a multi-centered group, so it is

1 unknown. There is multiple groups that applied, and  
2 so I don't know who is going to get that funding.

3 Q. Do you know of any ongoing research to look  
4 at the issue as to whether illicit drug use, like we  
5 saw was in two-thirds of the study population in the  
6 prior study, is in a -- more likely to produce kind of  
7 developmental delays if they exist than just use of  
8 prescription drugs within a prescription and under  
9 medical guidance?

10 MS. KEARSE: Object to form.

11 A. I'm not aware of data of that paper.

12 Q. Do you have an opinion on that issue?

13 A. If illicit use is associated with poor  
14 outcomes?

15 Q. Yes, sir.

16 A. I think it is multifactorial, and I don't  
17 know.

18 Q. Part of the factors would be how the kids are  
19 raised and how early interventions are, how effective  
20 they are?

21 A. What use and how long the use was.

22 Q. Right. So like chronic illicit use  
23 throughout the pregnancy, including into the third  
24 trimester, might be more likely to produce  
25 neurodevelopmental delays than somebody who took a

1     prescription opioid pursuant to prescription during  
2     the pregnancy?

3             A.    So if they had a more recent and a longer  
4     use, then I would expect more worse outcomes.

5             Q.    And also you'd expect worse outcomes with  
6     illicit use?

7             MS. KEARSE:   Object to form.

8             A.    Most likely, but it's unknown.

9             MR. ALEXANDER:   I would suggest that we take  
10    a break now so we can see how much time we have left.  
11    We might switch questioners and then we can figure out  
12    how much time is needed to finish up efficiently.

13            MS. KEARSE:   Okay.

14            THE VIDEOGRAPHER:   We are now going off  
15    record.   The time is 5:10.

16            (There was a brief.)

17            THE VIDEOGRAPHER:   We are now back on record.  
18    Time is 5:36.

19    BY MR. ALEXANDER:

20            Q.    Dr. Wexelblatt, is there any of your  
21    testimony that thus far you need to change or  
22    supplement in any way?

23            A.    No.

24            Q.    And during the break, did you have an  
25    opportunity to look at anything relating to the

1 Baldacchino paper that we were talking about  
2 earlier?

3 A. We did.

4 Q. And did you kind of go over some questions to  
5 be asked about that?

6 A. Did we go over questions?

7 Q. Yeah.

8 A. We went over the erratum that was  
9 published.

10 Q. Okay. The citation in your report was the  
11 actual paper I showed you, right?

12 A. It links to -- since it wasn't republished,  
13 that citation stays the same. So on the erratum, it  
14 was never republished, they just republished their  
15 results, which is the same exact link.

16 Q. Okay. Did you look at any other studies or  
17 anything during the break?

18 A. Just that one study.

19 Q. Have you looked at any additional materials  
20 during any of the breaks beyond what has been  
21 disclosed already?

22 A. I looked at an abstract that I got in my  
23 inbox about citations about breast milk and NAS, but  
24 that's about it.

25



1 (AmerisourceBergen-Wexelblatt-008 was marked  
2 for identification.)

3 Q. Okay. I'm going have to reach now, but I  
4 marked as Exhibit 8 a copy of the PowerPoint that we  
5 had earlier, I guess, Counsel.

6 We already went over this. This is just so  
7 that it's not unclear what we were referencing when we  
8 had the questioning earlier.

9 If you could just confirm that that is the  
10 PowerPoint --

11 A. Yep.

12 Q. -- that we went over earlier.

13 And so you stand by everything in that  
14 PowerPoint, right?

15 A. Yes.

16 Q. So if we can, I would like to go back to the  
17 Hall paper for one second. Some of language that we  
18 were discussing.

19 Before the break, we talked about the issue  
20 of the language where it says, significance of all  
21 other associations remained unchanged (data not  
22 shown). And that was in reference to basically doing  
23 an adjustment for Medicaid insured versus private pay,  
24 correct?

25 A. Medicaid insured or self-paying patients,

1 correct.

2 Q. But the comparison is to private, right?

3 MS. KEARSE: Objection.

4 A. We did -- multiple comparison was in the  
5 sensitivity analysis of Medicaid insured. Correct.  
6 We did it based on Medicaid insurance.

7 Q. Okay. So if you go to Table 1 for the NAS  
8 group, out of that 138, four they didn't know their  
9 insurance, 132 were public or self-pay, and only 2  
10 were private.

11 Do you see that?

12 A. I do.

13 Q. So based on what you noted about the -- the  
14 statistics here, would it be possible to do an  
15 adjustment for Medicaid status for the opioid exposure  
16 with NAS group given that there are only two private  
17 insured in that group?

18 A. So we corrected in the middle group the  
19 opioid exposure without NAS. So it's a direct -- you  
20 don't take out those are -- that you compare within  
21 that group of Medicaid insurance or not.

22 Q. The question was: Whether when one does an  
23 adjustment --

24 A. Uh-huh.

25 Q. -- for Medicaid status, whether that changes

1 the data.

2 And we said that for the opioid exposure  
3 without NAS doing that kind of adjustment changes the  
4 P value for some of the outcomes but not others.

5 A. So the way that you would do it is you would  
6 compare that 133 in the public with this 7,517, the  
7 public for the first -- the no detected exposures.  
8 You would throw out the private and the unknown in  
9 both, and say let's just look at Medicaid.

10 Q. Oh. So there wasn't an actual adjustment  
11 that was done for Medicaid status, it was just a  
12 sensitivity analysis?

13 A. The sensitivity -- exactly, that's what it  
14 states, is that within the sensitivity analysis.

15 Q. Okay. So was there an adjustment done in  
16 this paper for Medicaid status for any of the  
17 evaluations?

18 A. So yes. We did it with -- and found only  
19 changes with emotional disorders and speech disorders,  
20 and the significance are none of the others changed  
21 below our cutoff value of .05.

22 Q. Okay. So for the NAS group, was there an  
23 adjustment done for Medicaid status?

24 A. So we did it within both groups and found  
25 that the group that did change was only those opioid

1 exposed without NAS in those two subcategories,  
2 correct.

3 Q. So you're not doing an adjustment just  
4 focused on the opioid exposure with NAS group solely  
5 compared to the no detected exposure group based upon  
6 Medicaid status as the adjustment?

7 A. So I don't remember what all of the multiple  
8 comparisons were within the sensitivity analysis.  
9 Dr. Hall is our bio informatics Ph.D, so I would have  
10 to defer to him on what those actual mathematical  
11 situations were.

12 Q. Okay. So to know if essentially there was an  
13 adjustment for Medicaid status and it left the  
14 differences significant for opioid exposure with NAS  
15 with regard to developmental delay and these other  
16 criteria, we would need to ask Dr. Hall or get  
17 information from him, correct?

18 MS. KEARSE: Object to form.

19 A. We show that the significance is -- the  
20 significance only changed on those two out of all the  
21 other ones that we tried to look at.

22 Q. But you don't know what adjustments he did?

23 A. I don't know off the top of my head.

24 Q. Okay. Why don't we go back to your report,  
25 Exhibit 1, please.

1           Is your primary position -- this is paragraph  
2   9, but maybe you can answer without it.

3           Is your primary position in terms of the time  
4   you spent regional director of newborn care?

5           A. What is the question?

6           Q. Let me ask: In your professional life, is  
7   there an allocation of your time between your  
8   different roles and responsibilities?

9           A. A general breakdown, yes, there is.

10          Q. Can you give me the breakdown?

11          A. So I do 50 percent clinical, 20 percent  
12   administrative and 30 percent research, academic.

13          Q. And where is the clinical work done?

14          A. Multiple hospitals within our region.

15          Q. Is it broken up between them in any  
16   predictable way?

17          A. I go to -- I am on staff at eight different  
18   hospitals -- no, I take that back. More.

19                 Out of our 15 hospitals we cover, I'm on  
20   staff at 14. So I go to -- I'm on staff at 14 of our  
21   15 hospitals our group covers.

22          Q. And do you actually have your own patients or  
23   are you more kind of floating in and assisting  
24   others?

25          A. So we see patients. We make rounds on our

1 patients that are assigned to our group, which ends up  
2 being 90 percent of all of the births in our region.

3 Q. How many pediatricians are in your group?

4 A. Sixty-nine.

5 Q. And do you supervise them?

6 A. I supervise the pediatricians in our  
7 division, yes.

8 Q. So how many?

9 A. There's 20 of those.

10 Q. Okay. And so when you are doing rounds for  
11 the cases assigned to your group, does that mean you  
12 get roughly 5 percent of the cases?

13 A. No. So on that day at that hospital, it is  
14 either a hundred percent or 50 percent of patients,  
15 depending on which hospital we are at.

16 Q. Okay. That's for you personally?

17 A. It is for whoever is at that hospital.

18 Q. Okay. I'm asking about you.

19 A. Yes.

20 Q. When you go to a hospital, you're taking care  
21 of whoever the patients are that are there at that  
22 time assigned to your group?

23 A. Correct.

24 Q. And do you have a practice of seeing patients  
25 anywhere outside of what you described with the rounds

1 of the various eight plus hospitals in the group in  
2 the area?

3 A. The 14 hospitals, no.

4 Q. Have you had any subspecialty training within  
5 pediatrics?

6 A. No.

7 Q. Is there any kind of subspecialty  
8 certification available within pediatrics?

9 A. There is multiple, yes.

10 Q. Why don't you go to paragraph 15 of your  
11 report, please. So there is a description here of the  
12 various kind of general things that you did to form  
13 your opinions set forth in the report, correct?

14 A. Correct.

15 Q. And there is a reference here to  
16 "authoritative services such as..." and you say CDC,  
17 SAMHSA, ACOG, World Health Organization, ODHMS, ODH,  
18 ODM.

19 It's like alphabet soup there.

20 Do you see that?

21 A. I do.

22 Q. And so are you saying that the publications  
23 that you have cited from CDC, SAMHSA, World Health  
24 Organization, et al., are all considered  
25 authoritative?

1 A. Their organizations are.

2 Q. Oh, okay. But when you cited specific  
3 publications from them, did you try to only cite  
4 things that you thought were actually authoritative?

5 A. I had stuck to their general reviews, yes.

6 Q. When you did a literature search of  
7 scientific publications, do you know what you were  
8 looking for?

9 A. Mostly stuff that I've come across in my  
10 research, so it was mainly stuff that we have cited or  
11 published on.

12 Q. Pretty much things that you already knew?

13 A. Yeah.

14 Q. Did you have anybody who helped you in any of  
15 your work preparing your opinion in this case?

16 A. No.

17 Q. Did you have any meetings or discussions at  
18 all with anybody other than the lawyers?

19 A. No.

20 Q. The brief summary of opinions -- maybe we can  
21 cover a lot of this because I think we have throughout  
22 the day hit a bunch of these, but I have a couple of  
23 questions that may speed things up.

24 A: Under paragraph 15 says: Use and  
25 exposure of opioids among pregnant woman continues to



1 grow throughout the United States.

2 Your information for Ohio and Cuyahoga and  
3 Summit County in particular is that that usage has  
4 dropped over the last couple of years, correct?

5 MS. KEARSE: Object to form.

6 A. The usage of opioid exposure has not  
7 dropped.

8 Q. It continues to grow among pregnant women?

9 A. Yes.

10 Q. What has dropped is prescription use,  
11 right?

12 A. Correct.

13 Q. Okay. C says: Withdrawal signs develop --  
14 and this is related to NAS -- in 55 to 94 percent of  
15 opioid exposed infants.

16 And it says: With 30 to 65 percent of those  
17 infants requiring pharmacologic treatment for severe  
18 withdrawal.

19 You said that in your work the reliable  
20 number that you think is about, what, 42 percent?

21 A. That's our statewide data.

22 Q. For infants requiring pharmacologic treatment  
23 for severe withdrawal?

24 A. That is correct.

25 Q. Meaning that 42 percent of those who have

1 symptoms have a diagnosis of NAS?

2 A. That means that 40 percent of the patients  
3 that are having severe enough withdrawal to need  
4 pharmacologic treatment to get through it.

5 Q. Okay. So what percentage of all opioid  
6 exposed infants have NAS?

7 A. In our collaborative, we decided to call NAS  
8 only those that had the most severe withdrawal that  
9 need pharmacologic treatment.

10 So in that -- we came up with that definition  
11 in 2012. Now, some places describe NAS as babies  
12 needing a higher level of care, meaning they are  
13 admitted to Level 2 or 3 or 4 NICU, that that would be  
14 considered NAS because they needed increased level of  
15 care. So that's where the differentiation can  
16 happen.

17 Q. So what percentage of all pregnancies that  
18 involve opioid exposure result in the birth of a baby  
19 that will be diagnosed with NAS?

20 A. That's the 30 to 65 percent, depending on  
21 what definition you are using.

22 Q. But you think the right -- the right number,  
23 according to your definition, is 40 percent?

24 MS. KEARSE: Object to form.

25 A. By our definition in Ohio, yeah, we feel

1     confident that's our numbers.

2             Q.   You mentioned Level 3 and Level 4 NCIUs.

3                   How much of your time is spent in a NCIU?

4             A.   I spend my time in a Level 2 NCIU.

5             Q.   So do you ever spend any time in a Level 3 or  
6   Level 4 neonatal intensive care unit?

7             A.   Just consulting with patient -- doctors on  
8   NAS cases, but not seeing actual patients.

9             Q.   Are there some pediatricians who spend their  
10   time not in that arena?

11            A.   Not in a Level 3 or 4.

12            Q.   Okay.  Those are more -- those are a  
13   different subspecialty of medicine?

14            A.   That's -- neonatology fellowship is  
15   required.

16            Q.   And is that considered a subspecialty of  
17   pediatrics that we talked about?

18            A.   It is.

19            Q.   Is there a reason you chose not to do that?

20            A.   Time.

21            Q.   The percentage of NAS -- I guess for those  
22   who define NAS as requiring a higher level of care and  
23   therefore there is nonpharmacologic intervention, do  
24   you know what percentage of NAS babies respond  
25   favorably to nonpharmacologic intervention?

1           A.   So babies -- all babies respond to  
2 nonpharmacologic intervention.

3           Q.   Okay.   So as a general proposition, NAS  
4 treated either with pharmacologic intervention or  
5 nonpharmacologic intervention, according to the  
6 current standards, usually results in improvement?

7           A.   Correct.

8           Q.   D says:   The increasing number of women with  
9 opioid use disorder in Cuyahoga County and Summit  
10 Counties and the growing incidence of NAS is a  
11 significant public health issue.   The Counties will  
12 need to build upon existing programs and develop new  
13 multidisciplinary programs to improve the outcomes of  
14 women with opioid use disorder, mothers, and infants.

15                   So the statement here about "need to build  
16 upon existing programs," is that intended to suggest  
17 that you know what their existing programs are?

18           A.   At certain hospitals, yes.

19           Q.   What about all the programs in the county?

20           A.   I could never know all programs in all the  
21 counties.

22           Q.   I mean, you're not just suggesting the  
23 development of new programs at one or two hospitals in  
24 each county, are you?

25           A.   Depends on how many hospitals are in each

1 county.

2 Q. How many hospitals with Level 2 units are  
3 there in Cuyahoga County?

4 A. I'm not aware of that number.

5 Q. What about 3 or 4?

6 A. I don't know.

7 Q. What about Summit County, do you know about  
8 Level 2 units there?

9 A. I take that back about Level 3 or 4 at  
10 Cuyahoga. I think it is three, but I do not know if  
11 it's -- I think it is three.

12 Q. Okay.

13 A. And I think in Summit County it is one.

14 Q. Okay. So do you know the programs in place  
15 at any of the Level 3 -- the hospitals with a Level 3  
16 unit in Cuyahoga or Summit County?

17 A. I am familiar with some of the programs,  
18 yes.

19 Q. Okay. Enough to be able to opine in detail  
20 about what would need to happen to build upon the  
21 existing programs?

22 A. So yeah, they all have infant structures in  
23 place from our -- I know from our OPQC work, that they  
24 have been working on this actively.

25 Q. Do you know what all of the current programs

1 in place in Cuyahoga and Summit County are that focus  
2 us on prevention of NAS?

3 A. I do not know all of the county programs that  
4 are working on NAS.

5 Q. Do you know any of the names of any of the  
6 programs in place in Cuyahoga or Summit County that  
7 look at ways to reduce the incidence of maternal use  
8 of opioids and the resulting development of NAS in  
9 some portion of their offspring?

10 A. Yeah. So we have worked with the folks in  
11 those counties as part of OPQC MOMS Plus project. The  
12 actual names I couldn't tell you without going back  
13 and looking them up, but we have worked with them --

14 Q. Do you know --

15 A. -- in both counties.

16 Q. Do you know the names of any programs in  
17 place in either county?

18 A. The names of the actual programs?

19 Q. Yeah.

20 A. I probably couldn't tell you in our counties  
21 the actual specific names.

22 Q. E says: Preventing opioid exposure among  
23 women of childbearing age and pregnant women will  
24 greatly reduce the number of babies with narcotic  
25 exposure and reduce the need for treatment of NAS.

1                   Do you have any data specific to Cuyahoga or  
2     Summit County about the unintended pregnancy rate  
3     among woman using or abusing opioids?

4           A.   I don't know the specific rate of  
5     unintentional -- unintended pregnancy rate in those  
6     two counties.

7           Q.   Do you know what the programs are in place to  
8     prevent opioid use in that population or prevent  
9     unintended pregnancy in that population?

10          A.   I wouldn't know the specific names.

11          Q.   Do you know anything that they do, anything  
12     that those programs do?

13          A.   So I know the leaders of their regions who  
14     specify in their region and wouldn't know their exact  
15     names of their programs.

16                But myself, we just know what the concept is,  
17     which we have been shown, but to -- the difference  
18     between county X and Y doesn't really make a  
19     difference. It is the standardized approach, which  
20     has been shown to make the difference.

21          Q.   Okay. F says: Effective prevention  
22     programs will need to educate women of childbearing  
23     age about substance abuse prevention and raise  
24     awareness of the effects of opioid use prior to and  
25     during pregnancy, and provide counseling for women

1 being treated for opioid use disorder.

2 Do you know anything about the counseling  
3 programs in effect in Cuyahoga or Summit County  
4 relating to women and postpartum women in terms of  
5 anything relating to be substance abuse?

6 A. Once again, I just know their leaders in that  
7 region, not the actual names of their specific  
8 programs.

9 Q. So you don't have specific changes or tweaks  
10 to what they're already doing?

11 A. I would work with their -- their regional  
12 leader are the best ones to lead regional  
13 improvement.

14 Q. 8 (sic) says: Emergency rooms, health  
15 clinics, community drug treatment centers, and other  
16 service providers should expand screening programs in  
17 order to identify women in need of intervention and  
18 treatment referral.

19 And so like before, would you expand this to  
20 all substance abuse, not just opioids or opiates?

21 A. I think screening for all is great.

22 Q. Do you know anything about the screening  
23 programs in place in any emergency rooms, health  
24 clinics, community drug treatment centers or other  
25 service providers in Cuyahoga or Summit County in this



1     regard?

2           A.   I know that our now -- our Narcan initiative  
3     statewide started in emergency rooms up in Cuyahoga  
4     County, but that is about it for the specific names  
5     and treatment programs --

6           Q.   Like --

7           A.   -- screening services.

8           Q.   Do you know how many different emergency  
9     rooms, health clinic, community treatment centers, and  
10    other service providers who would be dealing with  
11    women in this context there are in Cuyahoga County?

12          A.   I would not know that number.

13          Q.   What about Summit County?

14          A.   I would not know that number.

15          Q.   To change the screening programs, there would  
16    there need to be a change of behavior by literally  
17    hundreds of different health care entities, correct?

18               MS. KEARSE:   Object to form.

19          A.   No.   It's something that would get a  
20    collaboration to -- to -- we usually do this -- I  
21    mean, we have made changes statewide on other issues  
22    addressing with NAS and put in protocols in 52  
23    hospitals.

24               And so we have a mechanism on how to spread  
25    and emerge protocols that we know are best practice.

1     So it would be the same thing with these facilities  
2     which are usually associated with a hospital. You  
3     would go by system and then have them spread it out.

4           Q. Okay. I think that we have talked about  
5     sub H, about recognizing barriers to treatment,  
6     correct

7           A. Correct.

8           Q. And we talked about I, about that you think  
9     that standardized assessments and treatment protocols  
10    improve outcomes, correct?

11          A. We have published on that, yes.

12          Q. And we have talked about it during the  
13    deposition, correct?

14          A. Yes.

15          Q. Do you have anything more to say about  
16    that?

17          A. Nope.

18          Q. J says: Universal maternal screening  
19    prenatally and testing at the time of delivery  
20    improves the identification of infants at risk for the  
21    development of NAS.

22                 We have talked about that one, too.

23                 Do you know the differences in screening  
24    practices and testing between the different healthcare  
25    facilities in Cuyahoga and Summit County?

1           A. I do know that they do universal screening in  
2   Cuyahoga County, and I'm -- not testing. And I'm  
3   pretty sure of -- that they're doing the same  
4   universal screening, not testing, in Summit County.

5           Q. Have you actually talked to your colleagues  
6   there about the -- why you think it would be a good  
7   idea for them to switch to the universal testing model  
8   that you have down here?

9           A. Yeah. Like we stated, this was a OPQC phone  
10   call that we did discuss.

11          Q. K says: Pharmacologic support for (sic)  
12   opioids has been shown to be the best treatment when  
13   medication is needed for withdrawal for babies with  
14   NAS.

15                 And we have talked about that, including your  
16   preference for buprenorphine compared to methadone or  
17   morphine, correct?

18          A. You said "for opioids" instead of "with  
19   opioids". So not all babies with opioids need to be  
20   treated, so I just want to fix that question that you  
21   stated. It's "with opioids," not "for opioids."

22          Q. Okay. Do you have anything you need to add  
23   on K?

24          A. No.

25          Q. L: Existing medication assisted treatment

1 programs should be expanded, along with coordinated  
2 supportive services that mitigate barriers women may  
3 try in accessing these -- I'm sorry -- experience in  
4 accessing these treatment.

5 So, we have talked about MAT programs a  
6 little bit in pregnant women.

7 And you said that you are not personally  
8 involved in administering them or prescribing that,  
9 correct?

10 A. Correct.

11 Q. And do you have an understanding of what is  
12 going on in Cuyahoga or Summit County now in terms of  
13 what coordinated support services they have available  
14 to address these issues and barriers for MAT?

15 A. I just know the national data of 20 to 26  
16 percent of women with substance use disorder are not  
17 getting -- are only getting MAT. So if that is a  
18 national number, I would assume that we would be  
19 seeing those same things in those two counties.

20 Q. But you think it should be better, right?

21 A. Oh, yeah.

22 Q. And I mean, that is a multifactorial issue of  
23 why 74 percent of women or any patient with a  
24 substance use disorder like the opioid disorders at  
25 issue here would actually seek treatment?

1 MS. KEARSE: Object to form.

2 A. Yeah. There's -- yeah, we would want to  
3 improve that.

4 Q. Okay. And so none of what actually what  
5 you're recommending would increase the percentage of  
6 women who are actually in MAT programs; is that  
7 right?

8 MS. KEARSE: Object to form.

9 A. I don't think that's a correct statement.

10 Q. Well, you hope that that could be happening,  
11 right, that you could increase the percentage of  
12 treatment --

13 A. I think with the right resources you could  
14 improve that number and make a difference.

15 Q. Have you spelled that out in the plan here on  
16 how to fix that?

17 A. How to expand by improving the access to  
18 buprenorphine -- I think M addresses that.

19 And going back to alleviating barriers, H  
20 addresses that, too.

21 Q. Is there any model that has been implemented  
22 anywhere in the country where the percentage has gone  
23 up significantly from the roughly 26 percent that you  
24 cited?

25 A. Yes. So our MOMS First program, which was

1 part of the Cures Act compared women that were in our  
2 four pilot sites, and compared to the -- those that  
3 were not, and found that woman that were in our pilot  
4 studies had improvement in behavioral therapy and  
5 maintaining MAT throughout their pregnancy.

6 Q. Is there a program that has been implemented  
7 that has published research that shows a significant  
8 increase in the percentage of women in MAT programs?

9 A. I -- the OPQC data from the first MOM part  
10 has not been published yet.

11 Q. Do you -- can you disclose how much you think  
12 that that MOM program has increased the access to  
13 MAT?

14 A. It is actually on the internet, so I'd have  
15 to look it up, the website; but, yes, it is available.

16 Q. Are you aware of any other published research  
17 on this issue?

18 A. No.

19 Q. Or publicly available research on this  
20 issue?

21 A. Just that program.

22 Q. O says: The effective long-term care of  
23 children and families impacted by opioids will require  
24 programs that provide family centered care, such as  
25 residential care for pregnant and postpartum women

1 with opioid use disorder, comprehensive pediatric  
2 care, such as regular preventative care for children;  
3 and developmental follow-up programs for children,  
4 which may include regular developmental screening,  
5 occupational therapy and physical therapy.

6 In terms of specifically what is currently  
7 going on in Cuyahoga and Summit County with regard to  
8 these types of programs, can you give us that level of  
9 detail?

10 A. So in Summit County, they have a family  
11 centered care approach and a centering approach that  
12 they're using for their mothers.

13 As far as following up a specialized NAS  
14 clinic, I'm not aware that they have that yet.

15 In Cuyahoga County, they are doing the family  
16 centered care also. They were the urban arm of our  
17 MOM One study. And they are also not involved in the  
18 developmental screening of NAS, but have applied for  
19 the HEAL grant through NIH to look at that program.

20 Q. What is the HEAL grant?

21 A. That was what we mentioned earlier with the  
22 NIH supported grant to look at MRIs and developmental  
23 outcomes of infants who are opioid exposed.

24 Q. So it says here "residential care for  
25 pregnant and postpartum women," and it talks about

1 various other types of care that could be provided.

2 Do you know who, other than the county, each  
3 county would need to participate to make this all  
4 happen?

5 A. So I know that we are utilizing that in our  
6 region and has shown improvement; so that's where we  
7 are at with the MOMS Plus program. We are trying to  
8 figure out which programs can be implemented in each  
9 region.

10 Q. So my question was inartful: To implement  
11 the changes that you are talking about in O or the  
12 long-term care plan in subsection O on page 6, who  
13 would need to participate other than the counties  
14 themselves?

15 A. They would need the hospital involvement and  
16 the physician involvement.

17 Q. Anything else?

18 A. Besides physician and hospital and OT and PT  
19 and screening programs, that would fall under the --  
20 like our NAS high-risk clinic.

21 Q. Do you know what standards are already in  
22 place for occupational therapy or physical therapy to  
23 help children with any of these developmental issues  
24 specifically in the context of opioid use?

25 A. Just when there is a need for referral is



1 when they become involved.

2 Q. So you don't know if they have any protocols  
3 specific for this type of issue?

4 A. No.

5 Q. Okay. But all of this stuff about long-term  
6 care of children in this context, is that all based  
7 upon specifically the idea of the -- or mitigating the  
8 potential long-term effects that we have been talking  
9 about with prior articles, or is this effective  
10 long-term care of children for the panoply of reasons  
11 why some child might have additional social services  
12 needed --

13 A. So we know that --

14 Q. -- in this context?

15 MS. KEARSE: Object to form.

16 A. So we know that early invention does help no  
17 matter what the etiology of the deficit is. And so  
18 knowing that this population is at a higher risk for  
19 any of these issues, we know that early intervention  
20 would help.

21 Q. So in layman's terms, what that means is that  
22 even if there is not a causal relationship between  
23 opioid use in utero and long-term effects, these are  
24 good suggestions anyway for a population at high risk  
25 for developmental delays and additional needs?

1 MS. KEARSE: Object to form.

2 A. I wouldn't agree with your first part of that  
3 statement; but I would agree that the second part of  
4 the statement is correct.

5 Q. So the long-term care stuff that is in place  
6 is because this is kind of a high-risk, high-need  
7 population even if it weren't for opioid use  
8 in utero

9 MS. KEARSE: Object to form.

10 A. That's known because we wouldn't know what  
11 this population would look like if they didn't have  
12 opioid exposure.

13 Q. So it's -- is it good to be able to identify  
14 this as a high-risk population because of continuing  
15 maternal use or the other sort of socioeconomic  
16 factors?

17 A. It's good because we know that we are  
18 starting to develop information that opioid use is  
19 associated with these longer term problems.

20 Q. Okay. P says: It is my opinion that an  
21 optimal maternal care program -- and is that all of  
22 what this is directed at, is getting an optimal  
23 maternal care program?

24 A. That's the goal, I think, of everybody,  
25 yes.

1           Q. -- would allow women with opioid use  
2 disorders to be identified during pregnancy and  
3 subsequently provided with prenatal care and other  
4 supportive services.

5           The program would provide for the development  
6 of an individualized treatment care plan for both  
7 mother and baby, as well as a discharge plan with home  
8 visitation, early intervention services and referrals  
9 to other supportive services.

10           The reference here to "individualized  
11 treatment care plan," obviously, you haven't written  
12 up what the algorithm would be or the guidelines would  
13 be for determining individual treatment care plans for  
14 mothers and babies in these situations, correct?

15           A. Correct.

16           Q. And this optimal maternal care program that  
17 you are talking about is not currently standard of  
18 care in Cuyahoga and Summit County, correct?

19           A. We are doing a lot of these things as part of  
20 the MOMS Plus project. All is -- all of them is not  
21 currently being done, but I think they are definitely  
22 doing some of them. And so the optimal is to  
23 incorporate all of them.

24           Q. And is some of this stuff that would be part  
25 of just the general transition over time to better

1 social services and better maternal care even if it  
2 weren't focused on an opioid use population?

3 MS. KEARSE: Object to form.

4 A. If it wasn't associated with an opioid use?

5 Q. Yes, sir.

6 A. Then I don't think they would need all of  
7 these plans.

8 Q. Is some portion of what you are recommending  
9 just improving general maternal and fetal outcomes in  
10 children even without any possible impact of the  
11 opioid use in utero?

12 A. We wouldn't need early intervention services,  
13 we wouldn't need a lot of this if they didn't have any  
14 opioid use. So, you can do it and it may change, but  
15 it probably wouldn't have any changes if there wasn't  
16 a need for it.

17 Q. Okay. This continues: Care would be  
18 coordinated through an interdisciplinary team that may  
19 include specialists in perinatology, neonatology,  
20 addiction medicine, psychiatry, social work, case  
21 management, and nutrition.

22 Referrals to the program would come from  
23 throughout the community, including emergency  
24 departments, obstetric triage, women's healthcare  
25 centers, family medicine providers, addiction medicine

1 providers, community drug treatment centers and  
2 hospitals.

3 Down here with the program that you have, is  
4 that where you get voluntary referrals from the  
5 community, from all of those sources?

6 A. We do receive referrals from those listed  
7 here, yes.

8 Q. Okay. And is any of the suggestion about how  
9 you should get referrals specific to Cuyahoga or  
10 Summit County or is this --

11 A. This would be statewide.

12 Q. Okay. And would you need to get these  
13 various entities, triage, women's healthcare, family  
14 medicine, etcetera, to buy in upfront to participate  
15 in an interdisciplinary team like this?

16 A. I think majority of them are probably already  
17 doing some aspects of it, just not all.

18 Q. The specialists that are listed here,  
19 perinatology, neonatology, addiction medicine,  
20 psychiatry, social work, case management, nutrition,  
21 are you an expert in any of those?

22 A. I don't have pediatrics on there, you are  
23 correct. I didn't -- I assumed I was writing this and  
24 it would be understood that I was part of this  
25 program. So I did leave out the word "pediatrics."

1           Q. But the ones you've listed here in the bottom  
2 of page 6, in paragraph P, these areas of expertise  
3 are not areas that you have expertise in?

4           A. No, but they are part of our collaboration.

5           Q. Okay. Maybe I can do it this way. The next  
6 section that talks about opioid use in the United  
7 States and Ohio, do you know any specific factors of  
8 what drove any of the opioid epidemic in Cuyahoga or  
9 Summit County beyond general observations about what  
10 often applies?

11           MS. KEARSE: Object to form.

12           A. I only have the statewide data on the  
13 increased numbers of deaths and the number of  
14 unintentional overdose deaths by Ohio, not by  
15 county.

16           Q. If you look through the various charts that  
17 you have on page 8 and 9, you'll see that the number  
18 of deaths -- I mean, these are all death focused --  
19 but the deaths from opioids and various, whether  
20 prescription or illicit, was climbing for a number of  
21 years, at least for the period of time for these  
22 charts.

23           Do you see that?

24           A. Yes.

25           Q. So when were the -- when was the increase in

1 death notable in Ohio according to these charts? Was  
2 it back in the mid-2000s? Was it by 2010?

3 When was it apparent that there was an  
4 increase in total opioid, if you lump them all  
5 together, deaths in Ohio?

6 A. I mean, any death is notable, so I don't know  
7 what you mean by when it was noticed.

8 Q. Well, I mean, I mean for you, you said in the  
9 early parts of this decade is when you started  
10 noticing an issue and you started focusing on  
11 additional research and statewide coordination to  
12 address what you saw would be a rising incidence of  
13 NAS and increasing issues of maternal opioid abuse,  
14 correct?

15 A. So, yeah. There has been a slow steady gain,  
16 and then there was a sharp peak in around 2010.

17 Q. So by around that time, based upon deaths and  
18 other indicia of increasing opioid use, including in  
19 women who ultimately got pregnant, it was all apparent  
20 around the state by no later than 2010?

21 MS. KEARSE: Object to form.

22 A. It is when we started addressing it. It  
23 doesn't mean it wasn't notable.

24 Q. I'm sorry? It was when you started  
25 addressing it?

1           A. Meaning we had -- funded research started  
2     coming, started discussion at that point, knowing that  
3     it takes a couple of years to get the funding in  
4     process. That's why the projects never started in  
5     2012 when we had our founding started.

6           Q. Okay.

7           A. It doesn't mean that we weren't addressing it  
8     prior.

9           Q. And so when was it that people like you first  
10    started noticing this was a problem and thinking about  
11    fixing it? Before 2010?

12           MS. KEARSE: Object to form.

13           A. Our data goes back to 2009, so I think that  
14    is when we really started making a concerted effort to  
15    start tracking it at the -- at our individual  
16    hospitals locally.

17           Q. And working towards --

18           A. Improvement.

19           Q. -- improvement?

20           Okay. And why don't you go forward in this  
21    to -- paragraph 26 is -- it says: Increases in opioid  
22    use among pregnant women includes increases in the use  
23    of prescription opioids, medication assisted  
24    treatment, increases in illicit drug use.

25           And it says: Studies have shown substance



1 use during pregnancy to be a ubiquitous problem  
2 affecting women across racial, socioeconomic status  
3 and age categories.

4 Do you see that?

5 A. I do see that.

6 Q. What we have seen from all of your studies  
7 and everything we looked at, is that it's  
8 predominately and more likely among the poorest part  
9 of the society and most likely essentially in poor  
10 Caucasians, non-Hispanic Caucasians in particular?

11 MS. KEARSE: Object to form.

12 A. That's what we are seeing in our state.

13 Q. Is there some reason that you didn't put that  
14 in this report?

15 A. No.

16 Q. Go to paragraph 28, please.

17 This is talking about risks of use by  
18 pregnant woman.

19 So you, obviously, don't recommend withdrawal  
20 during pregnancy, correct?

21 A. Correct.

22 Q. And then it says: Other risks to the baby  
23 include... is that a reference to withdrawal or just  
24 use in pregnancy?

25 A. Detoxification.

1 Q. Okay. And then this next sentence is what  
2 leads to the cite for Baldacchino that we have talked  
3 about at length, correct? About what you say  
4 long-term studies have shown?

5 A. That is correct, and it is stated in his  
6 erratum correctly.

7 Q. And it says: The mother may also be at risk  
8 -- increased risk of HIV, HBV, HCV, malnutrition and  
9 dangers associated with drug seeking behavior.

10 Have you seen an increase of HIV in your  
11 patient population?

12 A. So that is in referral to detoxification. So  
13 in our mothers for infants, we are seeing in Hamilton  
14 County an increased rate of HIV in our region;  
15 however, I don't know the breakdown of -- if it's  
16 affected pregnant women yet.

17 Q. And so HBV is hepatitis B?

18 A. Correct.

19 Q. And HCV is hepatitis C, and we've talked  
20 about that, correct?

21 A. We have.

22 Q. Okay. The issue of malnutrition in mothers,  
23 is that tracked at all in any of your work in terms of  
24 whether the women who are pregnant and abusing opioids  
25 or are on medication-assisted treatment also tend to

1 have malnutrition or other things during pregnancy  
2 that can affect pregnancy outcomes?

3 A. So that's with -- detoxification is what that  
4 risk is referring to.

5 Q. So do you see that in women who are not  
6 undergoing detoxification but are actively using  
7 during pregnancy?

8 A. I -- we don't measure for that.

9 Q. Do you see it?

10 A. Not usually.

11 Q. What about in -- what about tracking like the  
12 number of prenatal visits during pregnancy, if that's  
13 different depending on whether somebody is actively  
14 abusing illicit drugs, under drug medication-assisted  
15 treatment, or receiving another type of opioid  
16 prescription from a doctor and using it legally?

17 A. Can you repeat that? I dozed.

18 Q. Yeah. I won't take it personally.

19 So is there an association between the number  
20 of prenatal visits that a mother has and the health  
21 outcomes of the pregnancy?

22 A. We looked at that in our first paper.

23 Q. And do you see a difference of prenatal  
24 visits depending on whether the patient is using a  
25 prescription opioid under the care of a doctor for

1 something like pain, getting medication-assisted  
2 treatment, or actively using illicit drugs?

3 A. The only information I know we have from our  
4 MOMS Plus -- MOMS project was that being in a MAT  
5 program, in one of our focus MAT programs, improved  
6 the number of prenatal visits.

7 Q. Let's go to paragraph 30. It talks about --  
8 this is one of the places the ACOG statement is here.

9 And then I'm probably going to lateral to  
10 another questioner in a second.

11 Paragraph 30 talks about the ACOG statement  
12 that we went over, which is Exhibit 7 or 8, I think.

13 A. It is Number 7.

14 Q. Your statement here on top of page 13 is:  
15 The Committee's opinion is that the current standard  
16 of care for pregnant women with opioid dependence is  
17 referral for medication-assisted therapy with  
18 methadone, but emerging evidence suggests that  
19 buprenorphine also should be reconsidered.

20 Is there -- and then you can see it goes down  
21 -- later in this, there is another reference to this  
22 particular ACOG statement.

23 Is there anywhere in your report where you  
24 raise disagreements that you have with the ACOG  
25 statement relating to how they address long-term

1 consequences of maternal use of opioids while  
2 pregnant?

3 A. I did not address my long -- concerns with  
4 the long-term outcomes with ACOG.

5 Q. Again like I said, another questioner is  
6 going to ask some additional questions, but go to go  
7 to paragraph 44, and there is a chart right after on  
8 page 18, please, sir.

9 Do you see that the NAS rate in Summit County  
10 is now about twice what it is in Cuyahoga County?

11 A. I do.

12 Q. Do you know why that is?

13 A. We know that NAS is higher in rural areas  
14 than urban.

15 Q. Anything else?

16 A. No, I do not know why else.

17 Q. Are there other rates in other parts of Ohio  
18 that are higher than 13.6 percent for Summit County?

19 A. Yes.

20 Q. Are those more rural areas?

21 A. Yes.

22 Q. Do you know anything about the nature of the  
23 illegal drug trade in Cuyahoga County that might make  
24 it that there is either less medically-assisted  
25 treatment or more illicit drug use in pregnant

1 women?

2 A. I wouldn't know about the illegal drug  
3 trade.

4 Q. Do you know anything about the rates of  
5 medically -- MAT in Summit County and what drives  
6 that?

7 A. I do not know the rate of MAT in Summit  
8 County.

9 Q. Go to page 21, please. You're talking about  
10 the MOMS initiative and the MOMS Plus initiative.

11 Do you see those?

12 A. Number 56?

13 Q. Yes, sir. That whole section, 56 through 60.

14 And Cuyahoga and Summit are participating in  
15 MOMS Plus?

16 A. Correct.

17 Q. When did that start?

18 A. So MOMS first project started in 2014 to  
19 2016, and then it expanded -- we had one year off, and  
20 then picked it back up in 2018 for the MOMS Plus  
21 project.

22 Q. And do you think that the MOMS Plus project  
23 is helping even more than the MOMS project did?

24 A. We are still collecting data, so it is -- I  
25 can't answer that at this time.

1 Q. Do you think the MOMS project was helpful?

2 A. Yes.

3 Q. Do you think it should have been initiated  
4 earlier?

5 A. We wouldn't have known which -- if it worked  
6 without doing a pilot study and collecting data to  
7 know which is the best program, or if any program was  
8 better than the other. So, I think that we need to  
9 this as step-wide approach and find out what is the  
10 best way to tackle the problem.

11 Q. Where does the money for the MOMS Plus  
12 program come from?

13 A. I think that is through Department of  
14 Medicaid, but I do not know for sure.

15 I know our OPQC funding was through them, but  
16 I think -- I would have to look at the website to see  
17 who is funding them.

18 Q. What about the MOM program?

19 A. That was through Ohio Department of Addiction  
20 Medicine, I think, ODAM.

21 Q. Are you aware of any of the programs that are  
22 going on now in Cuyahoga or Summit County that relate  
23 to the subjects that we have here, these kind of  
24 recommendations that we have gone over in terms of  
25 broad categories where Cuyahoga County or Summit

1 County are actually paying for them with their own  
2 money?

3 MS. KEARSE: Object to form.

4 A. I don't know how the funding is happening.

5 Q. But the ones that you know about all involve  
6 funding from other sources, not the counties  
7 themselves, right?

8 A. The funding, a lot of it is mostly for the  
9 research component. So the actual programs themselves  
10 don't see any of the funding usually. It is more for  
11 the faculty doing the research component and data  
12 collection is where that funding is going to.

13 Q. Okay. So as you sit here today, can you  
14 offer testimony under oath that, in fact, Cuyahoga  
15 County or Summit County are currently expending any of  
16 their own money to do any of the programs that they  
17 have in these areas?

18 MS. KEARSE: Object.

19 A. I would not know their budget.

20 MR. ALEXANDER: Why don't we do a little  
21 pause while we change the questioner, and then  
22 depending on the questions from plaintiffs' counsel,  
23 there may be some follow-up.

24 MS. KEARSE: I think we need to see how many  
25 minutes left to whoever is --



1 THE VIDEOGRAPHER: You've got ten minutes.

2 MR. ALEXANDER: Why don't we go off the  
3 record to do the switch.

4 THE VIDEOGRAPHER: We are now going off  
5 record. The time is 6:27.

6 (There was a brief recess.)

7 THE VIDEOGRAPHER: We are now back on record.  
8 The time is 6:28.

9 EXAMINATION

10 BY MS. BARBER:

11 Q. Good afternoon, Dr. Wexelblatt. My name is  
12 Maureen Barber. I just have a few questions to ask of  
13 you.

14 Do you personally prescribe opioids for  
15 pain?

16 MS. KEARSE: Objection.

17 A. For pain outside of withdrawal for newborns?

18 Q. Yes. Do you prescribe any opioids for pain  
19 outside of the MAT opioids that you prescribe?

20 A. I don't prescribe MAT and I don't prescribe  
21 opioids outside of the hospital.

22 Q. Do any of the 69 pediatricians that you  
23 supervise prescribe opioids for anything other than  
24 the infants that you -- other -- for pain?

25 A. I don't know if some -- some of our

1     pediatricians do work in general pediatric clinics, so  
2     I couldn't answer for them.

3             Q.   Are -- you're familiar with a Dr. Stephen W.  
4     Patrick?

5             A.   I am.

6             Q.   You've cited to his work in your report?

7             A.   I have.

8             Q.   And you've relied on his work in support of  
9     your report that you have prepared in relation to this  
10    litigation?

11            A.   I have cited his papers, correct.

12            Q.   And you -- you trust his work?

13            MS. KEARSE:   Object to form.

14            A.   Yes.

15            Q.   And you believe it's accurate?

16            A.   Yes.

17            Q.   You would consider him an expert in the  
18    neonatal abstinence research, wouldn't you?

19            A.   I would.

20            Q.   Dr. Wexelblatt, all of the opinions that you  
21    plan to offer at trial are contained in your March 25,  
22    2019 expert report; isn't that correct?

23            A.   Yes, it is.

24            Q.   You don't intend to offer any opinion at  
25    trial that is not contained in that report, do you?

1           A. Besides stuff that has come up during this  
2 deposition.

3           Q. The -- any additional opinions that you have  
4 provided during this deposition that are not in your  
5 report, you don't intend to offer those opinions at  
6 trial, do you?

7           MS. KEARSE: Object to form.

8           Can you -- I think the record speaks for  
9 itself.

10          Q. If you change any of your opinions or intend  
11 to offer opinions at trial that are not contained in  
12 your March 25, 2019 report, then you will amend your  
13 report or supplement the report; isn't that correct?

14          MS. KEARSE: Object to form.

15          A. I think so, yes. I don't know the  
16 protocol.

17          MS. BARBER: I don't have any further  
18 questions.

19          MS. KEARSE: Why don't we take a break?  
20 Are you passing the witness?

21          MR. ALEXANDER: Yeah. I don't think we get  
22 to hand back.

23          MS. KEARSE: No. No. I'm just saying is  
24 there anyone else?

25          MR. ALEXANDER: I would say: Why don't we

1 start -- we're all here. I mean, why should we take  
2 another break?

3 MS. KEARSE: Because, Counsel, I'm going to  
4 take a break.

5 If you're now done with the witness, I'm  
6 going to take a break.

7 MR. ALEXANDER: Is it going to be another  
8 half an hour break or just a short break?

9 MS. KEARSE: You know, I actually don't know.  
10 So I'll let you know as soon as I come back.

11 I think I'm --

12 MR. ALEXANDER: I mean, just once we pass the  
13 witness, I don't think you're allowed to talk to him  
14 before you ask your questions. I don't think the  
15 protocol allows that.

16 MS. KEARSE: Can we go off the record,  
17 please.

18 THE VIDEOGRAPHER: Do you agree to go off the  
19 record?

20 MR. ALEXANDER: If you want to take a break,  
21 that's fine.

22 MS. KEARSE: Yeah.

23 THE VIDEOGRAPHER: We are now going off  
24 record. The time is 6:32.

25 (Recess taken.)

1 THE VIDEOGRAPHER: We are now back on record,  
2 and the time is 6:54.

3 EXAMINATION

4 BY MS. KEARSE:

5 Q. Good evening, Dr. Wexelblatt. Thank you for  
6 the time that you have put in so far today. I just  
7 have a couple of things I want to go over and make  
8 some clarifications for the record.

9 And for -- your CV that I think is Exhibit  
10 No. 3, that lists your education, your academic  
11 appointments and your training and education?

12 A. Yes.

13 Q. Okay. And you are board certified?

14 A. I am.

15 Q. And what are you board certified in?

16 A. Pediatrics.

17 Q. And you've published articles on your  
18 research in peer-reviewed literature related to opioid  
19 abuse?

20 A. I have. Sure.

21 MR. ALEXANDER: Objection. This is all  
22 leading, but go ahead.

23 MS. KEARSE: I'm just trying to speed it up.  
24 I can take more time if you need.

25 MR. ALEXANDER: It has nothing to do what I

1     need.

2           Q.   Have you published in the literature about  
3     opioid use in women of childbearing age?

4           A.   Yes.

5           Q.   Okay.  And that's reflected in your CV?

6           A.   It is.

7           Q.   Okay.  And you've reviewed other research in  
8     regard to those same issues?

9           MR. ALEXANDER:  Same objection.

10          A.   Yes.

11          Q.   Do you speak and present at medical  
12     conferences?

13          A.   I have.

14          Q.   And do you present on opioid exposure  
15     in utero

16          A.   I do.

17          Q.   And would you consider yourself an expert in  
18     maternal-fetal issues, including those related to  
19     opioid exposure?

20          A.   I would.

21          Q.   Okay.  And those are the things that you have  
22     testified about today?

23          A.   Yes.

24          Q.   Doctor, you testified and mentioned several  
25     times today about the OPQC.

1                   Can you tell the jury what -- what is the  
2   OPQC?

3           A.   So, the -- specific to the NAS project, it is  
4   a group of 52 hospitals that is working on quality  
5   improvement to opioid exposed infants.

6           Q.   And what does OPQC stand for?

7           A.   Ohio Perinatal Quality Collaborative.

8           Q.   And does that collaborative include  
9   specialists from all over the state?

10          A.   It does.

11          Q.   And as part of your work and research, did  
12   the OPQC make recommendations for treatment of NAS?

13          A.   It has.

14          Q.   Did they issue a protocol?

15          A.   We have.

16          Q.   And what was your role in the protocol?

17          A.   I was one of the lead authors in  
18   implementation of the -- and development of the  
19   protocol.

20          Q.   Doctor, I'm going to hand you what's been  
21   marked as Exhibit Number 9.

22                   Can you identify what I've just handed you as  
23   Plaintiff's Exhibit No. 9?

24                   (AmerisourceBergen-Wexelblatt-009 marked for  
25   identification.)

1 MR. ALEXANDER: Do you have a copy, Counsel?

2 MS. KEARSE: Yes, I do.

3 THE WITNESS: It's --

4 MS. KEARSE: And this was attached to his  
5 report, so I believe you should have a copy of it as  
6 well.

7 MR. ALEXANDER: Thanks.

8 Q. And what is Exhibit No. 9?

9 A. This is our updated protocol to -- on how to  
10 treat infants with NAS -- or with opioid exposure.

11 Q. And can you just briefly for the -- for the  
12 jury describe what the protocol is and why it is  
13 important to have a protocol treatment of NAS.

14 MR. ALEXANDER: Objection. Compound.

15 A. We have found that following a standardized  
16 protocol has shown improvement of care for infants  
17 with NAS.

18 And then this updated protocol was based on  
19 further testing and information that we gathered  
20 throughout our studying of this population.

21 Q. And how long have you been involved with the  
22 Ohio Perinatal Quality Collaborative?

23 A. That started in 2014 after the OCHA project  
24 ended.

25 Q. And have you published on the research and



1 studies by the OPQC?

2 A. Yes.

3 Q. And are those some of the publications you  
4 have either discussed today or referred to today in  
5 your testimony?

6 A. We have discussed it.

7 Q. Dr. Wexelblatt, we also discussed a lot today  
8 about different programs that could be implemented in  
9 order to improve public health outcomes.

10 Do you recall that?

11 A. I do.

12 Q. Would it be fair to say that the opioid  
13 epidemic is driving the need for programs you have  
14 identified in your report?

15 MR. ALEXANDER: Objection to form.

16 A. Yes.

17 Q. Doctor, you referred to the mother-child dyad  
18 several times today.

19 Do you recall that?

20 A. I do.

21 Q. Can you describe -- what do you mean by the  
22 "mother-child dyad"?

23 A. So you have to look at them -- the mother and  
24 the infant together. So even though I'm a  
25 pediatrician, I work directly with the mother.

1           And so do the obstetricians, they're working  
2   with the mother to produce a healthy infant. So when  
3   we work together on this, you can't just focus and  
4   silo only on one of them, you have to include both.

5           Q. And in your testimony today, is it fair to  
6   say that the opioid exposures have had the greatest  
7   impact on the issues that you think are most pressing  
8   for the mother-child dyad?

9           MR. ALEXANDER: Objection to form.

10          A. Yes.

11          Q. Doctor, early on, there was some discussion  
12   about off-label prescribing.

13                Do you recall that?

14          A. I do.

15          Q. Is it fair to say that off-label prescribing  
16   is more common among populations that are frequently  
17   excluded from clinical trials?

18                MR. ALEXANDER: Objection to form.

19          A. Yes.

20          Q. What are some of the populations that would  
21   be excluded from clinical trials?

22          A. Incarcerated individuals, pregnant women  
23   usually, and newborns.

24          Q. And why is that?

25          A. It is very hard -- to get FDA regulation, you

1     need to have vigorous double-blinded placebo trials.

2     And that is very hard in pregnant and neonates to get  
3     large enough sample sizes to develop that.

4             And especially in certain populations where  
5     doing a blinded nontreatment could be dangerous to the  
6     infant or newborn.

7             And when it comes to incarcerated  
8     individuals, it is more that it's a coercion to sign  
9     up for a study to lead -- to consent to a study  
10    without coercion being involved. That also makes it  
11    hard when you are talking about people with substance  
12    use disorder also, which fall into that category.

13            (AmerisourceBergen-Wexelblatt-0010 was marked  
14    for identification.)

15            Q. I'm going to show you a document. I'm just  
16    marking it for the record and then I'll pass it to you  
17    to see. I, apparently, only have one copy, but I'll  
18    lay the foundation and you can review it.

19            Doctor, earlier today, you were asked  
20    questions and referred to a paper by Dr. Patrick  
21    regarding the administrative data for neonatal  
22    abstinence syndrome.

23            Do you recall that?

24            A. I do.

25            Q. I'm marking what is Exhibit No. 10, and I'd

1 just ask you: Is that the article that you were  
2 referring to?

3 A. It is.

4 MS. KEARSE: Counsel, if you would like to  
5 take a look. I'm really just marking that for the  
6 record.

7 Q. Is that an article that you rely on in your  
8 opinions that you have given today?

9 A. I have.

10 Q. Okay. Doctor, you were also asked about an  
11 article and a citation -- an article by  
12 Dr. Baldacchino.

13 Is that how you pronounce it?

14 A. As far as I know.

15 Q. And is it fair to say that sometimes there is  
16 articles that are published that must be corrected  
17 later?

18 A. That is true.

19 Q. And if the article is republished, there may  
20 be a new citation?

21 A. That is correct.

22 Q. If the article has simply been corrected, it  
23 may not be -- and not republished, a citation might  
24 simply provide the same publication details as  
25 before?

1 A. That's correct.

2 Q. I'm handing you what I'm going to mark as  
3 Exhibit No. 11.

4 (AmerisourceBergen-Wexelblatt-0011 was marked  
5 for identification.)

6 Q. Doctor, if you can pull out Exhibit No. 6.

7 A. Yes.

8 Q. Is Exhibit No. 6 an article that  
9 Mr. Alexander showed you earlier that I laid out some  
10 objections regarding whether or not there was a  
11 current version of the article?

12 Do you recall that?

13 A. I do recall that.

14 Q. Okay. What is -- and for the record, Exhibit  
15 No. 6 is the Baldacchino article entitled  
16 "Neurobehavioral consequences of chronic inuterine  
17 [sic] opioid exposure to infants and preschool  
18 children: a systematic review and meta-analysis."

19 And this is a paper that you cite in your  
20 report; is that correct?

21 A. That is correct.

22 Q. Okay. Can you tell jury what Exhibit 11  
23 is?

24 A. So this was the corrected and the reference  
25 that we were referring to that showed that the

1 meta-analysis did show significant changes --  
2 statistically significant changes -- with long-term  
3 chronic exposure.

4 Q. And does it -- the title of this paper say:  
5 Erratum: Neurobehavioral consequences of chronic  
6 inuterine [sic] opioid exposure in infants and  
7 preschool children: a systematic review and  
8 meta-analysis?

9 A. It is that.

10 Q. And is this the correct version of the paper  
11 that you were relying on in regard to your opinions  
12 offered in this litigation?

13 MR. ALEXANDER: Objection to form.

14 A. It is.

15 Q. And on the front page of the paper, it  
16 actually talks about the correction?

17 A. It does.

18 Q. All right. And can you tell us specifically  
19 what was corrected in the paper in regards to the  
20 various tables?

21 A. Actually, all of the data.

22 Q. Can you be more specific?

23 A. Yeah. So it states that: The new conclusion  
24 of the paper show significant impairments, at a  
25 significant level of a P less than point -- 0.05 for

1 cognitive, psychomotor and observed behavioral  
2 outcomes for chronic intrauterine opioid exposed  
3 infants and/or preschool children compared to  
4 nonopioid infants and children. This is in contrast  
5 to a nonsignificant trend to poorer outcomes published  
6 -- reported previously.

7 Q. And this is the article that counsel refused  
8 to show you during your direct examination; is that  
9 correct?

10 MR. ALEXANDER: Objection to form.  
11 Mischaracterizes.

12 A. Yes.

13 MS. KEARSE: No further questions.

14 RE-EXAMINATION

15 BY MR. ALEXANDER:

16 Q. Some quick follow-up.

17 Dr. Wexelblatt, earlier you were asked some  
18 questions about off-label use and how it relates to  
19 clinical trials.

20 Do you remember those questions from  
21 plaintiffs' counsel, from like four minutes ago?

22 A. From plaintiff, yes.

23 Q. Plaintiffs' counsel over there.

24 A. Okay.

25 Q. Do you hold yourself out as an expert in

1 anything relating to FDA approval of drugs, the FDA  
2 process for clinical trials relating to drugs, any  
3 specific FDA issues?

4 A. I have been associated and part of some stuff  
5 of that nature, so I have an understanding.

6 Q. So do you hold yourself out in the community  
7 as somebody who can provide expert opinions about how  
8 to comply with FDA regulations relating to clinical  
9 trials?

10 A. No. We have a lawyer in our division who  
11 does that.

12 Q. Have you done any kind of study or research  
13 here about what the off-label approval practices are  
14 with regard to drug indications for studies, clinical  
15 studies, to figure out when and under what  
16 circumstances FDA does approve special population  
17 studies?

18 A. What was first part of that question?

19 Q. Have you done a study for the purposes of  
20 this case?

21 A. I have not done a study.

22 Q. So like -- I mean, there are clinical studies  
23 and there are drugs that are approved based on them  
24 that are specifically in infants, right?

25 A. I'm sure there are, yes.



1 Q. And there are definitely pediatric studies,  
2 right?

3 A. Yes.

4 Q. So, I mean -- go back for a second on the  
5 Baldacchino paper.

6 The citation here is not to the paper, the  
7 citation included here is a different citation to an  
8 erratum, correct?

9 That's what this thing is called, correct,  
10 erratum?

11 A. This is an erratum. Correct.

12 Q. It's the -- a fancy Latin word for the single  
13 version of error, right?

14 A. Correct.

15 Q. So at some point after the original paper was  
16 published and went through the peer-reviewed process,  
17 somebody figured out that they did their calculations  
18 wrong and they published a separate document that is  
19 basically four pages long, saying all of what we said  
20 before, we want to change because we realized we ran  
21 our numbers wrong, essentially --

22 A. Correct.

23 Q. -- right?

24 A. Correct.

25 Q. Okay. Did you cite this erratum in your

1 report?

2 A. That is -- the version that I was citing was  
3 the erratum version.

4 Q. So you meant to cite the erratum, but you  
5 cited the original paper?

6 A. So I cited the original paper with the  
7 erratum. I think the way I was able to access it  
8 through PubMed, it -- it has this as part of the  
9 original attached to it now.

10 Q. Okay. So just in terms of the sequence of  
11 this, this erratum came out in what year?

12 A. 2015.

13 Q. So the original paper was published in '14.  
14 We went over that. The erratum came out in 2015. And  
15 then we saw the work that went on in 2016 and 2017,  
16 resulting in the ACOG paper published in 2017, which  
17 we marked as an exhibit and discussed at length,  
18 correct?

19 A. That sounds correct.

20 Q. So this erratum about this meta-analysis and  
21 its results was before ACOG said that there wasn't  
22 essentially convincing evidence of long-term  
23 behavioral consequences from neonatal abstinence  
24 syndrome, right?

25 MS. KEARSE: Object to form.

1           A. I can't speak to why the authors didn't  
2 include this.

3           Q. I didn't ask you that.

4           I said the time sequence is that: This  
5 erratum was published about two years before the ACOG  
6 document said what it said that we went over  
7 earlier?

8           A. That is correct.

9           Q. And the gist of what ACOG had said,  
10 regardless of why those experts for ACOG and SAMHSA  
11 said what they said or what they reviewed, was  
12 essentially they didn't find convincing evidence of  
13 long-term behavioral or social effects associated with  
14 NAS, correct?

15          A. You included SAMHSA into that question, and I  
16 don't agree.

17          Q. I'm sorry. I misspoke. ASAM. This is a  
18 joint paper. I'm sorry. I didn't meant to interrupt  
19 you.

20          A. So I was just correcting that SAMHSA does not  
21 have that statement.

22          Q. So the statement that we went over we've been  
23 calling the ACOG Committee Opinion is actually a joint  
24 statement of the American College of Obstetricians and  
25 Gynecologists, and a separate medical association

1     called the American Society of Addiction Medicine,  
2     correct?

3             A.   Yes.   Those are the two adult components of  
4     that.

5             Q.   Okay.   As we said, you're not a member of  
6     either of those organizations, correct?

7             A.   You are correct.

8             Q.   And collectively, these deal on kind of both  
9     ends.   They deal with the prescription and use of  
10    opioids and they deal with issues relating to women of  
11    childbearing age, including the consequences of  
12    exposures during pregnancy, correct?

13            A.   They do deal with that.

14            Q.   Okay.   And so the statement that they -- they  
15    had that we talked about is that basically studies  
16    haven't they found significant differences in  
17    cognitive development between children up to five  
18    years of age, right?

19            A.   For the most -- they say:   For the most part,  
20    studies have not found significant differences of  
21    cognitive development.

22            Q.   And what they're talking about essentially  
23    the way these things are written, there is a thing,  
24    it's important to match for age, race and  
25    socioeconomic status, correct?

1           A. They say that is the major challenge when you  
2 are doing this literature search, yes.

3           Q. Okay. All right. So is there any portion of  
4 the testimony, other than relating to what you think  
5 the actual words are of the Baldacchino paper as  
6 amended by the erratum, that you gave on my  
7 questioning earlier today that you need to change or  
8 amend in any way?

9           A. Outside of that paper, I don't think there is  
10 anything.

11           MR. ALEXANDER: Well, those are all of the  
12 questions that I have for you.

13           I would state for the record that I think it  
14 is apparent that there are some potential  
15 supplementation and data issues, depending on what  
16 comes out in the future, and that we have discussed on  
17 specific studies relating to the testimony here today,  
18 but we will explore that outside of the deposition and  
19 don't need to do any of it on the record.

20                           RE-EXAMINATION

21           BY MS. KEARSE:

22           Q. I just have one follow-up question in regard  
23 to the -- what was just asked about.

24                   When you look at the ACOG -- when you look at  
25 the paragraph that Counsel keeps referring you to and

1     you go to the cited sources, is it fair that they're  
2     citing to sources from 1984 and in regard to what they  
3     looked at to make their statement about the long-term  
4     infant outcomes?

5                 MR. ALEXANDER:  Objection.  Asked and  
6     answered.

7                 A.  That is correct.

8                 Q.  So it's clear they didn't take into a -- they  
9     did not cite to -- to the papers that you've cited for  
10    your opinions in regard to that very same issues; is  
11    that fair?

12                A.  I agree with that statement.

13                MS. KEARSE:  No further questions.

14                THE VIDEOGRAPHER:  This adjourns the  
15    deposition of Dr. Scott L. Wexelblatt.

16                We are now going off record.

17                The time is 7:13.

18

19

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23

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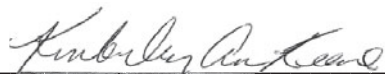
25

1  
2 CERTIFICATE

3  
4 I, Kimberley Ann Keene, a notary public,  
5 do hereby certify that the foregoing deposition of  
6 SCOTT WEXELBLATT, M.D.  
7 was taken before me at the time and place and for the  
8 purpose in the caption stated; that the witness was  
9 first duly sworn to tell the truth, the whole truth  
10 and nothing but the truth; that the deposition was  
11 taken before me stenographically and transcribed by  
12 me; that the foregoing is a full, true and complete  
13 transcript of the said deposition so given; that there  
14 was no request that the witness read and sign the  
15 transcript; that the appearances were as stated in the  
16 caption.

17 I further certify that I am neither counsel or of  
18 kin to any of the parties to this action, and am in no  
19 way interested in the outcome of said action.

20 Witness my signature this 20th day of April,  
21 2019. My Commission Expires on September 16, 2020.

22  
23 

Kimberley Ann Keene

24 Registered Professional Reporter  
25

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition  
4 over carefully and make any necessary  
5 corrections. You should state the reason  
6 in the appropriate space on the errata  
7 sheet for any corrections that are made.

8 After doing so, please sign  
9 the errata sheet and date it.

10 You are signing same subject  
11 to the changes you have noted on the  
12 errata sheet, which will be attached to  
13 your deposition.

14 It is imperative that you  
15 return the original errata sheet to the  
16 deposing attorney within thirty (30) days  
17 of receipt of the deposition transcript  
18 by you. If you fail to do so, the  
19 deposition transcript may be deemed to be  
20 accurate and may be used in court.

21

22

23

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1 - - - - -

E R R A T A

2 - - - - -

3

4 PAGE LINE CHANGE

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6 REASON: \_\_\_\_\_

7 \_\_\_\_\_

8 REASON: \_\_\_\_\_

9 \_\_\_\_\_

10 REASON: \_\_\_\_\_

11 \_\_\_\_\_

12 REASON: \_\_\_\_\_

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14 REASON: \_\_\_\_\_

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16 REASON: \_\_\_\_\_

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24 REASON: \_\_\_\_\_

25



1	LAWYER'S NOTES		
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